

EXHIBIT 93

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
PRESCRIPTION OPIATE)
5 LITIGATION) Case No. 1:17-MD-2804
6)
7) Hon. Dan A. Polster
THIS DOCUMENT RELATES TO)
8 ALL CASES)
9)

10 Friday, February 8, 2019
11 — — —

12 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
13 CONFIDENTIALITY REVIEW
14 — — —

15
16 Videotaped Deposition of GEORGE
SAFFOLD, held at Worthington Renaissance
17 Hotel, 200 Main Street, Fort Worth, Texas,
commencing at 9:08 a.m. on the above date,
18 before Susan Perry Miller, Registered
Diplomate Reporter, Certified Realtime
19 Reporter, Certified Realtime Captioner, and
Notary Public.

20
21
22 — — —
23 GOLKOW LITIGATION SERVICES
24 877.370.3377 ph | fax 917.591.5672
25 deps@golkow.com

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1 (Friday, February 8, 2019, 9:08 a.m.)
 2 THE VIDEOGRAPHER: All right,
 3 stand by. We are now on the record.
 4 My name is Brian Bobbitt. I'm a
 5 videographer for Golkow Litigation
 6 Services. Today's date is February 8,
 7 2019. The time is 9:08 a.m.
 8 This video deposition is being
 9 held in Fort Worth, Texas, in the
 10 National Prescription Opiate MDL,
 11 2804, case number, for the United
 12 States District Court, Northern
 13 District of Ohio, Eastern Division.
 14 The deponent is George Saffold.
 15 Does counsel want to identify
 16 themselves for the record?
 17 MS. KEECH: Erika Keech from
 18 Keller Rohrbach on behalf of the
 19 plaintiffs.
 20 MR. GOTTO: Gary Gotto from
 21 Keller Rohrbach.
 22 MR. GASTEL: Ben Gastel from
 23 Branstetter Stranch & Jennings on
 24 behalf of the Tennessee plaintiffs.
 25 MS. DURFEE: Laura Jane Durfee

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1 from Jones Day for Walmart.
 2 MS. BALASTER: Mary Balaster
 3 with Reed Smith on behalf of
 4 AmerisourceBergen Drug Corporation.
 5 MS. LaRUSSA: Cassandra
 6 LaRussa, Ropes & Gray, on behalf of
 7 Mallinckrodt LLC, SpecGx and the
 8 witness.
 9 MR. BERG: Nick Berg from
 10 Ropes & Gray.
 11 MR. SAFFOLD: George Saffold.
 12 THE REPORTER: And those on the
 13 phone, please?
 14 MR. MILLER: Hi, this is Jake
 15 Miller from Arnold & Porter on behalf
 16 of the Endo and Par defendants.
 17 MS. WIDAS: Alexandra Widas
 18 from Covington & Burling on behalf of
 19 McKesson.
 20 (Witness sworn by the
 21 reporter.)
 22 (Examination begins on next
 23 page.)
 24 --oOo--
 25 --oOo--

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1 PROCEEDINGS
 2 GEORGE SAFFOLD,
 3 having taken an oath to tell the truth, the
 4 whole truth, and nothing but the truth,
 5 testified as follows:
 6 EXAMINATION
 7 QUESTIONS BY MS. KEECH:
 8 Q. Good morning. Can you please
 9 state and spell your name for the record?
 10 A. Yes. My name is George
 11 Saffold, G-E-O-R-G-E, S, as in Sam, A, F as
 12 in Frank, F as in Frank, O-L-D.
 13 Q. And where do you currently
 14 reside?
 15 A. In North Richland Hills, Texas.
 16 Q. Are you currently employed?
 17 A. Yes.
 18 Q. Where?
 19 A. For VF Corporation.
 20 Q. And where is VF located?
 21 A. My office is located in
 22 Fort Worth.
 23 Q. And you understand that you're
 24 under oath today, right?
 25 A. Yes.

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1 Q. Are you taking any medication
 2 or is there any other reason that would
 3 interfere with your ability to testify
 4 truthfully and fully today?
 5 A. No.
 6 Q. Okay. And if I ask a question
 7 you don't understand, please let me know and
 8 I will try and rephrase it.
 9 A. (Nods head.)
 10 Q. Have you ever testified in a
 11 deposition or trial before?
 12 A. No.
 13 Q. I'm sure your counsel explained
 14 some general rules, but I'll also go over
 15 some as well. The court reporter here has
 16 the important job of transcribing everything
 17 that we're saying to each other, so it's
 18 important that we don't talk over one
 19 another, and give audible answers.
 20 So, please, if I ask a
 21 yes-or-no question, rather than shaking your
 22 head, please answer yes or no. Does that
 23 sound good?
 24 A. Yes.
 25 Q. And are you represented by

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1 counsel here today?
 2 A. Yes.
 3 Q. And who are they?
 4 A. They're from Ropes & Gray,
 5 Cassandra and Kevin.
 6 Q. Okay. From time to time, your
 7 counsel may object to questioning. Unless
 8 you get a clear instruction not to respond, I
 9 would ask that you respond to my question,
 10 okay?
 11 A. Yes.
 12 Q. And to the extent that you need
 13 a break, please let me know and I'll do my
 14 best to accommodate. I plan on taking breaks
 15 about every hour.
 16 A. Thank you.
 17 Q. Sir, I'm handing you what's
 18 been marked as Exhibit 1.
 19 (Mallinckrodt-Saffold Exhibit 1
 20 was marked for identification.)
 21 QUESTIONS BY MS. KEECH:
 22 Q. Do you recognize this document?
 23 A. Yes.
 24 Q. And what is it?
 25 A. It's a notice for the

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1 deposition today.
 2 Q. Okay. And when did you first
 3 see this document?
 4 A. Yesterday.
 5 Q. Would you turn with me to
 6 Schedule A? Do you see the request to bring
 7 documents?
 8 A. I'm sorry, can you give me a
 9 page? Oh, never mind. I do.
 10 Q. And did you search for
 11 documents that were responsive to this?
 12 A. Yes.
 13 Q. Did you look in your own
 14 personal paper or electronic files?
 15 A. Yes.
 16 Q. Did you ever use your personal
 17 e-mail to communicate with your work
 18 colleagues or customers about your work while
 19 you were employed with Mallinckrodt?
 20 A. No.
 21 Q. How about text messages?
 22 A. No.
 23 Q. Did you review your phone or
 24 personal computer for work-related text
 25 messages or e-mails?

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1 A. No. I did not review my phone
 2 nor my personal computer.
 3 Q. Did anyone ask you to do that?
 4 A. Yes. I did not because
 5 they're -- I don't have any documents from
 6 Mallinckrodt on my personal computer, and I
 7 did not have a phone that I kept with me
 8 after I left Mallinckrodt.
 9 Q. And what did you do to prepare
 10 for this deposition today?
 11 A. I met with counsel on two
 12 separate occasions.
 13 Q. Did you review any deposition
 14 transcripts or complaints or other papers
 15 filed in this litigation?
 16 A. No.
 17 Q. And when you met with your
 18 attorneys, was it in person?
 19 A. Yes.
 20 Q. Okay. And without telling me
 21 the content of your conversations, did you
 22 review documents with your attorneys?
 23 A. Yes.
 24 Q. And did reviewing documents
 25 refresh your recollection of any past events?

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1 A. Partially.
 2 Q. How so?
 3 A. The names of colleagues.
 4 Primarily that, just...
 5 Q. Did you speak with anyone else
 6 prior to this deposition, any former
 7 colleagues, friends still at the company?
 8 A. No.
 9 Q. And are you being reimbursed by
 10 anyone for your expenses in connection with
 11 this deposition?
 12 A. No.
 13 Q. Are you being compensated by
 14 anyone for your time in connection with your
 15 attendance or preparation for this
 16 deposition, including searching for your
 17 documents?
 18 A. No.
 19 Q. Did you graduate from college?
 20 A. Yes.
 21 Q. Where?
 22 A. Font Bonne University.
 23 Q. Can you spell that?
 24 A. F-O-N-T, B-O-N-N-E, University.
 25 Q. In what year?

<p style="text-align: right;">Page 18</p> <p>1 A. 2016.</p> <p>2 Q. Can you briefly describe your</p> <p>3 job history after high school to the present?</p> <p>4 A. Sure. After high school, I</p> <p>5 worked in a variety of jobs, a lot of</p> <p>6 restaurant jobs. I worked at Pasta House as</p> <p>7 a restaurant bartender, cook and waiter.</p> <p>8 It's where I met my future wife.</p> <p>9 From there, I worked at</p> <p>10 Macaroni Grill as a bartender trainer. And</p> <p>11 from there I became a development coordinator</p> <p>12 for Macaroni Grill and ultimately for Brinker</p> <p>13 International, which is the parent company of</p> <p>14 Macaroni Grill, where I went on the road and</p> <p>15 assisted with new unit development and</p> <p>16 openings of new units.</p> <p>17 Following that role, I became a</p> <p>18 temporary -- just kind of looking to make a</p> <p>19 career change, so I became a temporary</p> <p>20 employee with Manpower USA in data integrity;</p> <p>21 and then I was assigned Mallinckrodt, and I</p> <p>22 started working in data integrity at</p> <p>23 Mallinckrodt.</p> <p>24 From there, I became a customer</p> <p>25 service agent in our respiratory device</p>	<p style="text-align: right;">Page 20</p> <p>1 A. Yes. So I entered -- so it was</p> <p>2 a temporary -- it was a very -- it was an</p> <p>3 occupational job, so it had a lot of data</p> <p>4 entry. Mallinckrodt had purchased a</p> <p>5 respiratory company called Nellcor Puritan</p> <p>6 Bennett, and there was an effort to put them</p> <p>7 onto the same system as Mallinckrodt's</p> <p>8 system.</p> <p>9 And when they translated the</p> <p>10 addresses over, the -- not all the addresses.</p> <p>11 Customer addresses looked great. So my job</p> <p>12 was to go in and do things like retype an</p> <p>13 attention line.</p> <p>14 And then also in that role,</p> <p>15 about three hours a day I was assigned to</p> <p>16 when a customer service rep entered a request</p> <p>17 for a new customer address, my job was to</p> <p>18 search to see if we actually already had that</p> <p>19 address in our database.</p> <p>20 Q. Thank you. And what year did</p> <p>21 you begin employment with Mallinckrodt?</p> <p>22 A. Around 1999.</p> <p>23 Q. And do you recall when you</p> <p>24 transitioned to customer service?</p> <p>25 A. September of 1999, I believe.</p>
<p style="text-align: right;">Page 19</p> <p>1 division. Following that, I was a supervisor</p> <p>2 of critical care customer service, which was</p> <p>3 medical device.</p> <p>4 Following that, I was manager</p> <p>5 of distributor logistics for Mallinckrodt on</p> <p>6 the medical device side. Then I became</p> <p>7 director -- oh, I'm sorry. Then I was</p> <p>8 manager of distribution operations for</p> <p>9 Mallinckrodt imaging and respiratory.</p> <p>10 Following that, I became director of customer</p> <p>11 service for Mallinckrodt imaging solutions</p> <p>12 and respiratory monitoring solutions.</p> <p>13 After that, I became director</p> <p>14 of Mallinckrodt pharmaceutical and</p> <p>15 respiratory. Then I became director of</p> <p>16 Mallinckrodt pharmaceutical global customer</p> <p>17 service. And then in March of 2017, I left</p> <p>18 the company.</p> <p>19 Q. Thank you. Before joining</p> <p>20 Mallinckrodt, did you have any experience in</p> <p>21 the pharmaceutical industry?</p> <p>22 A. No.</p> <p>23 Q. Can you tell me a little bit</p> <p>24 more about your role in data integrity? What</p> <p>25 did that involve?</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. So how long would you estimate</p> <p>2 that you were in the data integrity group?</p> <p>3 A. Six-ish months.</p> <p>4 Q. Okay. Do you hold any</p> <p>5 professional licenses or certificates?</p> <p>6 A. Yes.</p> <p>7 Q. And what are they?</p> <p>8 A. I'm a Six Sigma Business</p> <p>9 Process Green Belt.</p> <p>10 Q. And where did you obtain that</p> <p>11 certification?</p> <p>12 A. Tyco Healthcare.</p> <p>13 Q. Have you taken any courses</p> <p>14 related to distribution of controlled</p> <p>15 substances?</p> <p>16 A. No.</p> <p>17 Q. Are you familiar with the</p> <p>18 claims asserted in this litigation?</p> <p>19 A. In a general sense only.</p> <p>20 Q. And generally speaking, what do</p> <p>21 you understand the claims to be?</p> <p>22 A. I understand that there are</p> <p>23 several -- there's a multiparty group</p> <p>24 asserting that a large number of defendants</p> <p>25 are responsible for opioids.</p>

<p style="text-align: right;">Page 22</p> <p>1 Q. Anything else?</p> <p>2 A. No.</p> <p>3 Q. Okay. Do you have a view as to</p> <p>4 the merits of any of the claims?</p> <p>5 A. No.</p> <p>6 Q. And when did you learn about</p> <p>7 this litigation?</p> <p>8 A. I think I heard a little bit</p> <p>9 about it on 60 Minutes, and then -- then</p> <p>10 certainly as I was contacted relevant to this</p> <p>11 case.</p> <p>12 Q. Do you recall when you saw that</p> <p>13 60 Minutes episode?</p> <p>14 A. No. And to be clear, I did not</p> <p>15 see the 60 Minutes episode. I just saw the</p> <p>16 advertisement for the 60 Minutes episode. I</p> <p>17 never watched it.</p> <p>18 Q. Thanks for clarifying.</p> <p>19 Any idea as far as how many</p> <p>20 years ago that was or how recently you saw</p> <p>21 the advertisement?</p> <p>22 A. I -- no.</p> <p>23 Q. Okay. And thank you for</p> <p>24 running through your positions at</p> <p>25 Mallinckrodt earlier.</p>	<p style="text-align: right;">Page 24</p> <p>1 to 2009, you were given no training at</p> <p>2 Mallinckrodt with regard to the Controlled</p> <p>3 Substances Act?</p> <p>4 A. Yes.</p> <p>5 Q. And can you describe the</p> <p>6 training that you were given?</p> <p>7 A. Yes. Our members of our</p> <p>8 compliance team, DEA compliance team, talked</p> <p>9 about the importance of compliance, my</p> <p>10 obligations, as in my role, and the</p> <p>11 obligations of my team members.</p> <p>12 Q. And what did you understand</p> <p>13 those obligations to be?</p> <p>14 A. Well, the first was to process</p> <p>15 orders carefully and diligently, paying</p> <p>16 attention to 222 forms and making sure those</p> <p>17 were accurate.</p> <p>18 And the second was to ensure</p> <p>19 that from the moment we accepted an order to</p> <p>20 the moment it was delivered that it was</p> <p>21 secure, it was done properly and securely,</p> <p>22 and that if any anomaly or anything took</p> <p>23 place, like I said, a delivery exception, it</p> <p>24 was our responsibility to report that</p> <p>25 immediately.</p>
<p style="text-align: right;">Page 23</p> <p>1 For each position, did your</p> <p>2 duties require you to be familiar with the</p> <p>3 Controlled Substances Act or regulations</p> <p>4 thereunder?</p> <p>5 A. No.</p> <p>6 MR. BERG: Object to form.</p> <p>7 A. No.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. In any of your positions at</p> <p>10 Mallinckrodt, were you given any training</p> <p>11 regarding the Controlled Substances Act or</p> <p>12 any of its regulations?</p> <p>13 A. Yes.</p> <p>14 Q. And can you please describe</p> <p>15 which positions required you -- or provided</p> <p>16 that training?</p> <p>17 A. As director of customer service</p> <p>18 for pharmaceuticals.</p> <p>19 Q. Any other positions?</p> <p>20 A. No.</p> <p>21 Q. And what year did you become</p> <p>22 director?</p> <p>23 A. In 2009.</p> <p>24 Q. 2009.</p> <p>25 So is it fair to say that prior</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. So you had a responsibility to</p> <p>2 report anomalies. Can you give an example of</p> <p>3 the type of anomaly?</p> <p>4 A. Yes. If a recipient of our</p> <p>5 product called and said, hey, I'm short a</p> <p>6 bottle of pills, we would immediately report</p> <p>7 that to the DEA.</p> <p>8 I'm sorry. We really -- I</p> <p>9 wouldn't report it to the DEA. I would</p> <p>10 report it to our DEA compliance team, and I</p> <p>11 believe they would report it to the DEA.</p> <p>12 Q. When you would raise issues</p> <p>13 with the DEA compliance team internally at</p> <p>14 Mallinckrodt, would you then receive</p> <p>15 verification that that issue was actually</p> <p>16 reported to the DEA?</p> <p>17 A. I don't recall.</p> <p>18 Q. So fair to say you trusted that</p> <p>19 the DEA compliance team would follow through</p> <p>20 with whatever you raised to them?</p> <p>21 MR. BERG: Object to form.</p> <p>22 A. Yes.</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. And can you describe your job</p> <p>25 description as a customer service</p>

<p style="text-align: right;">Page 26</p> <p>1 representative and director?</p> <p>2 A. Which particular -- I had</p> <p>3 several roles. Each was a different job.</p> <p>4 Q. Actually, if you could walk</p> <p>5 through each of them, that would be great.</p> <p>6 A. Sure. As a customer service</p> <p>7 representative in the respiratory division of</p> <p>8 Mallinckrodt, I assisted distributors and</p> <p>9 hospitals, home healthcare providers, with</p> <p>10 tracheostomy and tracheotomy tubes,</p> <p>11 temperature monitoring devices and pulse</p> <p>12 oximetry. So mainly it was order entry,</p> <p>13 letting people know where their orders were,</p> <p>14 and then very low-level troubleshooting,</p> <p>15 helping them with returns.</p> <p>16 Q. And your role as customer</p> <p>17 service director?</p> <p>18 A. In which -- I was a customer</p> <p>19 service director in several groups.</p> <p>20 Q. In each of your capacities.</p> <p>21 A. So as customer service director</p> <p>22 for respiratory and monitoring solutions and</p> <p>23 imaging solutions, I had a few different</p> <p>24 groups. On the respiratory side, we were</p> <p>25 mostly selling medical devices -- no,</p>	<p style="text-align: right;">Page 28</p> <p>1 respiratory group out of my -- mine and</p> <p>2 transferring them over to another location,</p> <p>3 so I worked on that.</p> <p>4 And then I also assumed</p> <p>5 responsibility for our active pharmaceutical</p> <p>6 ingredients group and our dosage group.</p> <p>7 Q. So when you assumed</p> <p>8 responsibility for active pharmaceutical</p> <p>9 ingredients or API and dosage, can you</p> <p>10 describe your responsibilities in that role</p> <p>11 or that capacity?</p> <p>12 A. Sure. The API customer service</p> <p>13 team accepted orders from manufacturers and a</p> <p>14 lot of that product is made to order, and so</p> <p>15 then coordinated with our manufacturing team,</p> <p>16 our planning team, on the timing and delivery</p> <p>17 of that.</p> <p>18 And then the dosage group</p> <p>19 sold -- primarily sold, you know, dosage</p> <p>20 pharmaceuticals to wholesalers, and that team</p> <p>21 accepted orders, advised on order status and,</p> <p>22 you know, assisted with returns, if any.</p> <p>23 Q. So in your role as director of</p> <p>24 global customer service, who did you report</p> <p>25 to?</p>
<p style="text-align: right;">Page 27</p> <p>1 exclusively selling medical devices, so</p> <p>2 pulse oximetry, tracheostomy, tracheotomy</p> <p>3 tubes. I'm sure I'm missing some too, but a</p> <p>4 lot of devices, a lot of those are</p> <p>5 disposable.</p> <p>6 Then in the imaging side, we</p> <p>7 had two unique businesses. One is contrast</p> <p>8 media, so dyes used for X-ray, right, and so</p> <p>9 I was assist -- so there our customers were</p> <p>10 hospitals and imaging centers and</p> <p>11 distributors.</p> <p>12 And then on the nuclear -- then</p> <p>13 we also had a nuclear medicine division, so</p> <p>14 there we are making nuclear medicine,</p> <p>15 radioactive, for procedures. We're</p> <p>16 chartering planes and flying that medicine to</p> <p>17 hospitals and then getting couriers to drive</p> <p>18 it to the hospital so that it can be given to</p> <p>19 the patient while it's still actively</p> <p>20 radioactive. And that was my respiratory and</p> <p>21 imaging job.</p> <p>22 Then in '99, as director of</p> <p>23 pharma and respiratory and imaging, I also --</p> <p>24 so I retained those three groups and then</p> <p>25 worked on the planned separation of the</p>	<p style="text-align: right;">Page 29</p> <p>1 A. So in my role as -- I reported</p> <p>2 to -- in my role as director of global</p> <p>3 customer service, I reported to the director</p> <p>4 of global supply chain.</p> <p>5 Q. And who was that?</p> <p>6 A. George Morrison.</p> <p>7 Q. And was he -- were you his</p> <p>8 direct report when you left Mallinckrodt?</p> <p>9 A. Yes.</p> <p>10 No, I'm sorry. Right before I</p> <p>11 left Mallinckrodt, we restructured, and I was</p> <p>12 no longer his direct report at that time.</p> <p>13 Q. And who was your supervisor at</p> <p>14 that point in time?</p> <p>15 A. Kassie Harrold.</p> <p>16 Q. And did she evaluate your</p> <p>17 performance?</p> <p>18 A. No.</p> <p>19 Q. Did George Morrison?</p> <p>20 A. Yes.</p> <p>21 Q. And how was the evaluation</p> <p>22 conducted? How frequently?</p> <p>23 A. Annually.</p> <p>24 Q. Is there a written record of</p> <p>25 your annual review?</p>

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1 A. Yes. I would -- well, I would
2 assume so, but I don't have any knowledge if
3 it was -- you know, of where it is or whether
4 it was retained.
5 Q. Okay. So you don't know who
6 would maintain those performance evaluations?
7 A. No.
8 Q. And when you were evaluated,
9 were you evaluated based on any particular
10 metrics?
11 A. Yes.
12 Q. Do you recall what they were?
13 A. Yes. Call answer rate, so the
14 percentage of calls answered within 30
15 seconds; order accuracy, as an expression of
16 Sigma.
17 Q. Any other factors?
18 A. None that I can remember.
19 Q. Do you recall if your
20 performance was at all tied to sales?
21 A. Yes, I do recall. No, it was
22 not.
23 Q. And you indicated that you left
24 Mallinckrodt in March of 2017. Is that
25 correct?

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1 A. Yes.
2 Q. And what were the circumstances
3 under which you left?
4 A. We had done a lot of
5 restructuring, and so I left as part of that.
6 Q. Was it voluntary?
7 A. I don't know. I had asked -- I
8 had said I would be interested in leaving and
9 making a career change. At the same time, I
10 don't know -- you know, you don't really get
11 to choose that, right, so I don't know how to
12 answer that.
13 Q. When you left Mallinckrodt, did
14 you receive a severance payment?
15 A. Yes.
16 Q. And what was the amount of the
17 severance?
18 A. It was -- I was there for 17
19 years, and I received [REDACTED] for
20 every year. So [REDACTED] of salary.
21 Q. Did you have a severance
22 agreement?
23 A. Yes.
24 Q. And did it limit what you were
25 allowed to say about Mallinckrodt?

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1 A. I don't believe so.
2 Q. Were there any other
3 restrictions in the severance agreement?
4 A. I don't recall the specifics of
5 the severance agreement.
6 Q. Do you still have it?
7 A. I do.
8 Q. Did you disclose it?
9 A. Yes.
10 MS. KEECH: And, Counsel, I
11 would ask that if that document hasn't
12 already been disclosed that you please
13 do so.
14 MR. BERG: Understood. We'll
15 look into it.
16 QUESTIONS BY MS. KEECH:
17 Q. So up until you left
18 Mallinckrodt, did you consider yourself a
19 successful director of global customer
20 service?
21 A. I never really thought about
22 it.
23 Q. Did you ever think about your
24 performance as a Mallinckrodt employee?
25 A. Yes.

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1 Q. And what did you think about
2 your performance?
3 A. I think I was a good employee.
4 Q. You complied with workplace
5 rules?
6 A. Yes.
7 Q. And you did your job the way
8 that Mallinckrodt expected you to do your
9 job?
10 A. Yes.
11 Q. Would you say that you were
12 well regarded by your peers at Mallinckrodt?
13 A. I'd say it was mixed, like any
14 other place.
15 Q. What about your supervisors?
16 Do you have an impression of what their view
17 of you was?
18 A. Yes.
19 Q. And what was that?
20 A. Based on my performance
21 evaluations, my supervisors considered me
22 anywhere from a good employee to a
23 superlative employee.
24 Q. And would you say that you're
25 detail-oriented?

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1 A. No.
2 Q. So not detail-oriented, but
3 order accuracy was one of your performance
4 metrics?
5 MR. BERG: Object to form.
6 A. The order accuracy of my team
7 was one of our performance metrics.
8 QUESTIONS BY MS. KEECH:
9 Q. Were you personally evaluated
10 with regard to order accuracy?
11 A. I did not enter orders after --
12 you know, after I became supervisor of
13 customer service.
14 Q. Okay. So as global customer
15 service director, how -- strike that.
16 In your capacity as global
17 customer service director, did you get to
18 know your customers?
19 A. Not very many.
20 Q. Were there some that you were
21 more well acquainted with than others?
22 A. Yes.
23 Q. And do you recall which
24 customers?
25 A. Yes. I'd refer to them as the

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1 Big Three; McKesson, Cardinal, and ABC. Then
2 also the nuclear medicine customers, the
3 pharmacists. That's such a unique business
4 and a very small community; one learns them
5 fairly... and then definitely
6 internationally, my international customers,
7 but it's more as affiliates, right, so the
8 international affiliates, I got to know them.
9 Q. Can you describe your
10 relationship with each of the Big Three?
11 A. Professional.
12 Q. Both professionally and
13 personally if --
14 A. No, that was my description.
15 It was a professional relationship.
16 Q. Did you ever attend dinners
17 with any individuals from the Big Three?
18 A. As part of a group, probably
19 over the course of several years, maybe five
20 to seven.
21 Q. And do you recall who else was
22 present at those dinners?
23 A. Not specifically, no. But it
24 usually involved -- it always involved a
25 larger group of people from both

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1 organizations.
2 Q. How would you define "large
3 group"? More or less than five?
4 A. More than five.
5 Q. And did you get to know the Big
6 Three customers?
7 A. No. I mean, not well or...
8 Q. What did you know about their
9 companies?
10 A. Going through each, one is
11 efficiency. We are very interested in
12 efficiency and doing things right, and we
13 shared that mutual interest. I think that
14 was universal.
15 Other than that, I don't really
16 recall anything specific about any of these
17 companies or really the individuals in them.
18 Q. No specific recollections about
19 any of the Big Three companies?
20 A. No.
21 Q. Did you seek to retain
22 customers?
23 A. No.
24 Q. So no effort was put into
25 retaining customers as the director of

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1 customer --
2 A. Correct. We had no initiative
3 based on customer retention.
4 Q. And which customers were you
5 responsible for?
6 A. In which role?
7 Q. In your last role at
8 Mallinckrodt.
9 A. In my last role at
10 Mallinckrodt, I was responsible for our
11 nuclear medicine pharmacies, our
12 international affiliates, our -- quite
13 simply, anyone who placed an order with
14 Mallinckrodt. That's probably a better
15 answer.
16 Q. Do you recall what your salary
17 was when you started at Mallinckrodt?
18 A. No, not specifically. It was
19 under [REDACTED] a year, I remember that.
20 Q. Did you receive raises while
21 you were there?
22 A. Yes.
23 Q. And can you walk me through
24 your raises that you received and when you
25 received them, to the extent that you

Page 38

1 remember?

2 A. I can't remember my raises. I

3 don't remember any of the circumstances

4 around my raises.

5 Q. Do you recall what your salary

6 was when you left Mallinckrodt?

7 A. Yes.

8 Q. And what was it?

9 A. About [REDACTED].

10 Q. Did you also receive bonuses

11 while you were there?

12 A. Yes.

13 Q. And do you recall the size of

14 the bonus when you left?

15 A. No. I'd need to know

16 specifically what bonus you are talking

17 about.

18 Q. Did you receive multiple

19 bonuses?

20 A. Yes.

21 Q. Can you describe to me the

22 various bonuses you received?

23 A. Yes. I received usually a

24 yearly bonus. Also, there was one time, and

25 I'm unsure of the year, I received a

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1 retention bonus. And then -- and usually the

2 bonuses were by year, but sometimes for

3 restructuring purposes and everything, that

4 bonus got paid out because we changed a

5 fiscal year or something, it got paid out,

6 like it wasn't a full year.

7 And then when I left, I

8 think -- I'd have to check, but I think I may

9 have gotten a partial prorated kind of bonus

10 at my departure, or maybe really prior to my

11 departure but around the same time.

12 Q. I'm handing you what's been

13 marked as Exhibit 2, bearing Bates stamp

14 MNK-T1_0007219867.

15 (Mallinckrodt-Saffold Exhibit 2

16 was marked for identification.)

17 QUESTIONS BY MS. KEECH:

18 Q. Do you recognize that document?

19 A. Yes.

20 Q. And is that the retention bonus

21 that you just referred to?

22 A. It is.

23 Q. What were the circumstances

24 surrounding this retention payment?

25 A. We were trying to execute a

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1 spin of Mallinckrodt from Covidien. A few

2 other directors in the supply chain had

3 already left. The supply chain lead was

4 leaving and so they -- and so I was, you

5 know, asked to -- I was offered this.

6 Q. And prior to receiving this

7 retention bonus, did you express

8 dissatisfaction to anyone at Mallinckrodt

9 regarding your employment there?

10 A. I don't recall.

11 Q. In the second paragraph on this

12 document, it says: Because your knowledge

13 and skills are critical to the company during

14 this transition period, you are eligible for

15 a payment of [REDACTED].

16 What knowledge and skills did

17 you have that you believe were critical to

18 Mallinckrodt?

19 MR. BERG: Object to form.

20 A. I don't know. I mean, I didn't

21 ask for this payment and I was a bit -- I was

22 very pleased to get it.

23 QUESTIONS BY MS. KEECH:

24 Q. Okay. Thank you.

25 So going back to the customers,

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1 how much information was available to you

2 about Mallinckrodt's customers?

3 A. Some. And it would depend on

4 the role, so I guess in which role are you

5 referring to?

6 Q. As the director of global

7 customer service.

8 A. So I saw -- what would be

9 available to me would be pretty much to whom

10 we shipped and to whom we've sent invoices.

11 Q. Can you describe your level of

12 interaction with the Big Three customers?

13 A. Limited. Professional.

14 Q. Did you have a role in

15 generating opioid sales?

16 A. No.

17 Q. Did anyone under customer

18 service review peculiar or unusual orders?

19 A. Yes.

20 Q. And who did that?

21 MR. BERG: Object to form.

22 A. Certainly the manager of -- it

23 would depend on the time period. But

24 generally, in my role as director of global

25 pharmaceuticals, the manager of dosage

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1 customer service and -- did.
2 QUESTIONS BY MS. KEECH:
3 Q. And during what time period did
4 the manager of dosage review peculiar orders?
5 A. I'm not 100% sure I could tell
6 you.
7 Q. Prior to 2009?
8 A. I couldn't tell you anything
9 about that prior to 2009.
10 Q. Did customer service
11 representatives ever monitor peculiar or
12 suspicious orders?
13 A. No.
14 Q. Are you aware that Mallinckrodt
15 had a duty to design and implement a
16 Suspicious Order Monitoring program?
17 MR. BERG: Object to form.
18 A. Yes.
19 QUESTIONS BY MS. KEECH:
20 Q. And were you aware of that duty
21 when you were employed by Mallinckrodt?
22 MR. BERG: Object to form.
23 A. Yes.
24 QUESTIONS BY MS. KEECH:
25 Q. Who informed you of that duty?

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1 A. Our global DEA compliance lead.
2 Q. And do you recall when you
3 learned of this duty?
4 A. Not specifically, but during
5 the onboarding process from moving from
6 respiratory into imaging, so July-ish of
7 2009.
8 Q. And were you personally
9 involved in monitoring suspicious orders
10 during your employment at Mallinckrodt?
11 A. No.
12 Q. Were you involved in auditing
13 any of Mallinckrodt's customers?
14 A. No.
15 Q. Do you know whether
16 Mallinckrodt conducted audits of its
17 customers?
18 A. Yes.
19 Q. And what do you understand the
20 purpose of an audit to be?
21 A. I don't know.
22 Q. Do you know how Mallinckrodt
23 determined who to audit?
24 A. No.
25 Q. Do you recall which entities

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1 that Mallinckrodt audited?
2 A. No.
3 Q. So you just indicated you don't
4 know the purpose of an audit. Do you know
5 the mechanics of an audit, in general terms?
6 A. I know the mechanics of an
7 audit when I undergo an audit. I do not know
8 the mechanics of a customer audit.
9 Q. So you don't know what
10 Mallinckrodt would look at?
11 A. No.
12 Q. Who it spoke with?
13 A. Huh-uh.
14 Q. Okay. You're not aware of
15 whether Mallinckrodt had a specific audit
16 procedure to follow?
17 A. No, I'm not aware of any audit
18 procedures, other than our own -- other than
19 what were Mallinckrodt's own internal audit
20 so -- but I'm not aware of any other audit.
21 Q. When you describe
22 Mallinckrodt's own internal audit, what are
23 you referring to?
24 A. Our people from our internal
25 audit company. Our audit group, not company,

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1 looking at my function, right, to make sure
2 we were complying with financial regulations.
3 Q. So you are aware of a group
4 within Mallinckrodt that was auditing your
5 capacity?
6 A. Yes.
7 Q. But fair to say you're not
8 aware of whether Mallinckrodt audited any of
9 its customers?
10 A. I was aware that Mallinckrodt
11 did audit customers, but I have no detailed
12 knowledge or actually any knowledge at all
13 what that really meant, means.
14 Q. Okay. And were you aware that
15 in 2010, Mallinckrodt identified various
16 indirect customers who were purchasing from
17 multiple Mallinckrodt distributors?
18 A. No.
19 Q. Did you ever make a
20 determination that a customer had suspicious
21 orders?
22 A. No.
23 Q. Are you aware of whether
24 Mallinckrodt ever made a determination that
25 any of its customers had suspicious orders?

Page 46

1 A. No.

2 Q. Are you aware that

3 manufacturers and distributors of narcotics

4 must comply with the Controlled Substances

5 Act?

6 MR. BERG: Object to form.

7 A. Yes.

8 QUESTIONS BY MS. KEECH:

9 Q. Are opioids narcotics?

10 MR. BERG: Object to form.

11 A. Yes, I think so.

12 QUESTIONS BY MS. KEECH:

13 Q. And Mallinckrodt manufacturers

14 opioids, correct?

15 A. Yes.

16 Q. And are you familiar with the

17 requirements of the Controlled Substances Act

18 as it relates to a manufacturer of controlled

19 substances?

20 A. No. Only as the -- no.

21 Just -- I'm not, really.

22 Q. So earlier, when you indicated

23 that members of DEA compliance talk about the

24 importance of compliance, did they ever

25 discuss the Controlled Substances Act?

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1 A. In general terms, yes. Like,

2 hey, you have to comply, and it's very

3 important to do so. And here's what we think

4 you need to do to comply, and take that

5 seriously. And that's kind of the context

6 and the thrust of the message.

7 Q. Do you feel that your training

8 was adequate with regard to what your duties

9 and responsibilities were?

10 A. Yes.

11 Q. But you don't recall what any

12 of those duties and responsibilities are?

13 MR. BERG: Object to form.

14 A. I understand my duties and

15 responsibilities and how they relate to

16 compliance.

17 QUESTIONS BY MS. KEECH:

18 Q. Can you describe your duties

19 and responsibilities as they relate to

20 compliance?

21 A. Yes. Our first responsibility

22 was to make sure that the order placed was a

23 valid order, so we checked against -- well,

24 first of all, we maintained systems and

25 processes that could validate the order,

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1 whether it was a manual or electronic order.

2 Second was to protect the

3 integrity of the supply chain. So, you know,

4 so there's a certain amount of

5 confidentiality that we maintained so that

6 way bad guys couldn't find out where product

7 was going, right. And that, it was even for

8 my systems, so I then made sure that people

9 who hadn't passed a DEA background check

10 didn't have access to this information.

11 And then the third was to

12 report any -- any discrepancy. So if it was,

13 you know, a misdelivery, mis-shipment,

14 somebody tampered with a package, right, I'd

15 make sure that my team was reporting that to

16 our DEA team and recording that. So that was

17 very important.

18 And then really, anything --

19 you know, and then to collaborate, you know,

20 with other members of Mallinckrodt kind of at

21 the direction of the DEA compliance team to

22 make sure we're -- any other area where we

23 can demonstrate compliance.

24 Q. Are you familiar with the term

25 "closed system" for opioid distribution?

Page 49

1 A. No.

2 Q. This means that only people or

3 entities that are registrants under the

4 Controlled Substances Act can be involved in

5 the distribution of controlled substances.

6 MR. BERG: Object to form.

7 QUESTIONS BY MS. KEECH:

8 Q. Does that sound familiar?

9 MR. BERG: Object to form.

10 A. The term and your statement

11 don't sound familiar, but the concept, yes,

12 that's -- that was very important.

13 QUESTIONS BY MS. KEECH:

14 Q. And that concept, would you

15 agree that the purpose of that is to minimize

16 theft and diversion of controlled substances?

17 A. Yes.

18 Q. And would you agree that a

19 registrant's failure to meet its obligations

20 under the Controlled Substances Act can

21 result in controlled substances being

22 diverted from legitimate channels?

23 A. I don't know. I'm not really a

24 controlled -- you know, I'm not an expert on

25 the Controlled Substances Act or diversion,

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1 so it's tough for me to speculate kind of
2 downstream. I just understood my obligation,
3 right, was to...

4 Q. Would you agree that a
5 manufacturer that sells controlled substances
6 to distribute -- to distributors who then
7 recklessly distribute opioids is engaged in
8 diversion?

9 MR. BERG: Object to form.

10 A. I'm not really an expert on
11 even what diversion is, right. So my view of
12 diversion is like you get it from point A to
13 point B and make sure that it's where --
14 it's going where it's supposed to and that
15 it's approved and compliant.

16 QUESTIONS BY MS. KEECH:

17 Q. So what do effective controls
18 to prevent diversion mean to you?

19 MR. BERG: Object to form.

20 A. Well, I certainly can't speak
21 to all aspects of diversion. I'm not sure
22 there's even a universal definition. So I'm
23 not sure I can answer the question, really.

24 QUESTIONS BY MS. KEECH:

25 Q. The Controlled Substances Act

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1 requires a Suspicious Order Monitoring
2 system, correct?

3 MR. BERG: Object to form.

4 A. I don't know.

5 QUESTIONS BY MS. KEECH:

6 Q. What does the term "Suspicious
7 Order Monitoring system" mean to you?

8 MR. BERG: Object to form.

9 A. So in the context of my role,
10 my understanding is it's required by the DEA
11 to -- that Mallinckrodt as an entity is
12 required to have a Suspicious Order
13 Monitoring program and that my team
14 interacted with our DEA compliance team to
15 kind of ensure compliance with that.

16 QUESTIONS BY MS. KEECH:

17 Q. And Mallinckrodt had a
18 Suspicious Order Monitoring program, correct?

19 A. Yes.

20 Q. Did Mallinckrodt have a duty to
21 identify suspicious orders of Mallinckrodt
22 products?

23 MR. BERG: Object to form.

24 A. I think that was a requirement
25 of the Suspicious Order Monitoring program,

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1 but I'm not, you know -- I'm not an expert on
2 that.

3 QUESTIONS BY MS. KEECH:

4 Q. Do you know if they had a duty
5 to report suspicious orders to the DEA?

6 MR. BERG: Object to form.

7 A. Yes. I understood that they
8 did have a duty to report suspicious orders
9 to the DEA.

10 QUESTIONS BY MS. KEECH:

11 Q. And Mallinckrodt's distributor
12 customers are called direct customers,
13 correct?

14 A. I don't -- I don't think that's
15 a statement you can make universally. We had
16 a lot of lines of business, and so people
17 used those terms really poorly.

18 So, no, people may have called
19 them that, but they may not have as well.

20 Q. How did you refer to
21 Mallinckrodt's distributor customers?

22 A. As distributors and
23 wholesalers.

24 Q. Okay. How about customers that
25 those distributors and wholesalers then sold

Page 53

1 product to?

2 MR. BERG: Object to form.

3 A. Can you repeat that?

4 QUESTIONS BY MS. KEECH:

5 Q. Sure.

6 Did you have a term for the
7 customers of Mallinckrodt's distributor
8 customers?

9 A. Yes. Like distributors and
10 wholesalers. Oh, for their customers?

11 Q. Correct.

12 A. Okay, I'm sorry. Not one that
13 would apply to them universally, right. So
14 if a distributor sold it to a pharmacy, we
15 would say -- you know, I would call them a
16 pharmacy. Or if they sold them to a clinic,
17 a clinic or to a PBM, I'd say a PBM.

18 So I'm not sure there was a --
19 I'm not familiar with like a nomenclature for
20 that group of people you're referring to.

21 Q. Did you ever hear either the
22 term "indirect" or "downstream" customer for
23 those entities?

24 A. I don't recall that.

25 Q. We've been going about an hour.

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1 Would now be a good time for a break?
2 MR. BERG: Sure.
3 MS. KEECH: Okay. Maybe five
4 minutes. Okay.
5 THE VIDEOGRAPHER: Stand by.
6 Off the record at 10:08.
7 (Recess taken, 10:08?a.m. to
8 10:22?a.m.)
9 THE VIDEOGRAPHER: All right,
10 stand by. The time is 10:22. Back on
11 the record.
12 QUESTIONS BY MS. KEECH:
13 Q. Would you agree that there is
14 an opioid crisis or prescription drug abuse
15 epidemic facing the country?
16 MR. BERG: Object to form.
17 A. Yes.
18 QUESTIONS BY MS. KEECH:
19 Q. Have you ever received a
20 communication from Mallinckrodt regarding the
21 existence of an opioid epidemic?
22 A. I don't recall.
23 Q. In what year did you realize
24 there was an opioid epidemic?
25 A. I can't name a specific year.

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1 I think it was -- I'd maybe call it like more
2 of like a gradual understanding.
3 Q. And when did you develop this
4 understanding?
5 MR. BERG: Object to form.
6 A. I'm not sure I know exactly
7 when.
8 QUESTIONS BY MS. KEECH:
9 Q. Was it while you were still
10 employed by Mallinckrodt or after leaving?
11 A. While I was employed.
12 Q. Did you ever discuss it with
13 anyone at Mallinckrodt?
14 A. No.
15 Q. And are you aware of whether
16 Mallinckrodt products have contributed to
17 this problem?
18 A. No.
19 Q. Mallinckrodt sold oxy
20 15 milligrams and oxy 30 milligrams, correct?
21 A. Yes.
22 Q. And Mallinckrodt's distributor
23 customers purchased millions of these
24 products from Mallinckrodt, correct?
25 A. Yes.

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1 Q. And did you ever come to
2 realize at some point in time that
3 Mallinckrodt's Suspicious Order Monitoring
4 system that Mallinckrodt was using to
5 identify diversion by its distributor clients
6 was not adequate?
7 A. No.
8 MR. BERG: Object to form.
9 A. I'm sorry, I'm not sure you
10 heard me. No.
11 QUESTIONS BY MS. KEECH:
12 Q. Thank you.
13 Do you agree that as a director
14 of customer service, it was important for you
15 to keep up to date on the news about opioid
16 abuse and diversion?
17 A. No.
18 Q. Did you think it was important
19 for you to know whether any of Mallinckrodt's
20 customers were sanctioned for their business
21 practices related to distribution of
22 Mallinckrodt's products?
23 A. For me to know?
24 Q. Yes.
25 A. No.

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1 Q. And are you familiar with the
2 term "migration" as it applies to opioid
3 products?
4 A. No.
5 Q. Have you ever heard the phrase
6 "Oxy Express" or "Blue Highway"?
7 A. I've heard the phrase "Oxy
8 Express."
9 Q. And what do you believe that
10 term or phrase to signify?
11 A. Working off of recall, I think
12 it means from like -- I think like up from
13 Florida, up -- kind of up into the northeast
14 corridor, there's like a highway or
15 something.
16 Q. And were you aware while you
17 were at Mallinckrodt that a significant
18 number or volume of opioids, particularly
19 oxycodone, was first being sent to Florida
20 where they would then migrate to other
21 states?
22 MR. BERG: Object to form.
23 A. No.
24 QUESTIONS BY MS. KEECH:
25 Q. Were you aware that large

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1 volumes of Mallinckrodt product were going to
2 Florida?
3 A. No.
4 Q. Ever hear anyone discuss
5 Florida as it relates to an opioid epidemic
6 or problem distributors?
7 A. I've never heard, really, as it
8 relates to opioid epidemic. Yes, as it
9 relates to problem distributors.
10 Q. And what was the context of
11 those communications?
12 A. I can -- you know, to the best
13 that I can recall, it was that there are some
14 distributors who are -- who have been
15 suspended for not following best practice or
16 being out of compliance, and some of their
17 locations were in Florida or maybe they were
18 shipping to Florida, so...
19 (Mallinckrodt-Saffold Exhibit 3
20 was marked for identification.)
21 QUESTIONS BY MS. KEECH:
22 Q. I'm handing you what's been
23 marked as Exhibit 3, bearing Bates numbers
24 MNK-T1_000290150. And this is an e-mail sent
25 from Victor Borelli on Wednesday, July 29th,

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1 2009. You are on the "to" line.
2 Do you recall receiving this
3 e-mail?
4 A. I don't.
5 Q. Do you have any reason to doubt
6 its authenticity?
7 A. Oh, no.
8 Q. Turning to the second page, can
9 you read aloud the third paragraph down
10 beginning with the phrase "Statistics show"?
11 A. "Statistics show an alarming
12 problem facing America. Prescription drug
13 abuse, which has held steady over the past
14 five years according to the Partnership for a
15 Drug-Free America, with nearly one in five
16 teens abusing prescription medications to get
17 high."
18 Q. And can you read --
19 A. Oh. "Prescription drug abuse
20 is a significant problem in this country."
21 Q. Thank you.
22 Do you agree with that
23 statement, that prescription drug abuse is a
24 significant problem in this country?
25 A. Yes.

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1 Q. Do you agree that the illegal
2 distribution of controlled substances
3 currently has a substantial and detrimental
4 effect on the health and general welfare of
5 the American people?
6 MR. BERG: Object to form.
7 A. I'm sorry, can you repeat that
8 question?
9 QUESTIONS BY MS. KEECH:
10 Q. Do you agree that the illegal
11 distribution of controlled substances
12 currently has a substantial and detrimental
13 effect on the health and general welfare of
14 the American people?
15 MR. BERG: Object to form.
16 A. I'm not sure I know enough
17 about the drivers of the prescription drug
18 abuse problems in this country to have
19 formulated an opinion on that.
20 QUESTIONS BY MS. KEECH:
21 Q. Okay. And turning to the first
22 page of this document, it indicates that
23 south Florida has become the largest supplier
24 of illegal prescription drugs in this
25 country.

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1 Were you aware of that?
2 MR. BERG: Object to form.
3 A. No. Like at the time I -- at
4 what time?
5 QUESTIONS BY MS. KEECH:
6 Q. In 2009.
7 A. So, no, prior to receipt of
8 this; and then, yes, after receipt.
9 Q. So beginning in 2009, after
10 receiving this e-mail, you were aware that
11 south Florida had become the largest supplier
12 of illegal prescriptions in the country?
13 A. Yes.
14 Q. Okay. And were you also aware,
15 as Victor Borelli wrote, that doctor shopping
16 occurs in the state of Florida?
17 A. No firsthand knowledge.
18 Q. Do you have any reason to doubt
19 Victor Borelli's statement there that doctor
20 shopping was happening in Florida?
21 MR. BERG: Object to form.
22 A. No.
23 QUESTIONS BY MS. KEECH:
24 Q. Okay. Are you familiar with
25 the term "pill mill"?

Page 62

1 A. Yes.

2 Q. And what do you understand that

3 to mean?

4 A. Well, I think I've seen it used

5 in a variety of contexts. Generally it --

6 where I've heard the term "pill mill," it has

7 referred to a place that does either one of

8 two things; writes a lot of prescriptions for

9 pain medication, or fills a lot of

10 prescriptions for pain medications.

11 Q. Thank you.

12 (Mallinckrodt-Saffold Exhibit 4

13 was marked for identification.)

14 QUESTIONS BY MS. KEECH:

15 Q. I'm now handing you what's been

16 marked as Exhibit 4, a document bearing Bates

17 stamp MNK-T1_0007179935.

18 (Document review by witness.)

19 QUESTIONS BY MS. KEECH:

20 Q. This is an e-mail sent from

21 Karen Harper to you on October 31st, 2009,

22 regarding fentanyl fanny packs.

23 Do you recall receiving this

24 e-mail?

25 A. I don't recall the specifics of

Page 63

1 it.

2 Q. The last sentence or

3 second-to-last sentence of Ms. Harper's

4 e-mail says: Fentanyl pops accidentally

5 obtained by children would lead to certain

6 overdose and death.

7 MR. BERG: Object to form.

8 QUESTIONS BY MS. KEECH:

9 Q. Are you aware that people have

10 died from overdoses of opioids?

11 A. Yes.

12 Q. Okay. And do you agree with

13 Karen's statement that if Mallinckrodt

14 products got into the wrong hands, it could

15 result in death?

16 MR. BERG: Object to form.

17 A. Yes, definitely some

18 Mallinckrodt products.

19 QUESTIONS BY MS. KEECH:

20 Q. Thank you. You can set that

21 aside.

22 Are you familiar with the term

23 "suspicious order"?

24 A. Yes.

25 Q. And what do you believe that to

Page 64

1 mean?

2 A. You know, I guess in my

3 experience, it -- really, it's what's flagged

4 by our compliance and monitoring team as an

5 order that we should report and investigate.

6 Q. Do you know what

7 characteristics Mallinckrodt was looking for

8 in order to flag such orders?

9 A. Not specifically, but

10 characteristics of the anomalous.

11 Q. Okay. Did Mallinckrodt

12 order -- excuse me. Did Mallinckrodt flag

13 orders of unusual size?

14 A. I don't recall.

15 Q. Did Mallinckrodt flag orders

16 deviating substantially from a normal

17 pattern?

18 A. You know, I'm not familiar with

19 how orders were flagged, and I also think the

20 program may have changed even during my

21 tenure there. So I'm not sure I can answer

22 that with any kind of confidence.

23 Q. Okay. So fair to say you don't

24 know whether orders of unusual frequency were

25 flagged either?

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1 A. Yes, that's fair.

2 Q. Okay. Were you ever trained to

3 detect suspicious orders for prescription

4 medications?

5 A. No.

6 Q. Are you familiar with the term

7 "peculiar order"?

8 A. Yes.

9 Q. And can you define that,

10 please?

11 A. Sure. Peculiar orders were

12 orders that attributes were outside of what

13 maybe we would expect to be receiving from

14 the certain -- from a certain customer at a

15 certain time, and they required investigation

16 and more information to determine whether or

17 not we would, you know, accept the order or

18 flag it further.

19 Q. So what types of scenarios

20 would result in a flag or, in other words,

21 they're outside of what Mallinckrodt would

22 expect?

23 A. Well, again, I'm not an expert,

24 right, so I just knew that these orders were

25 flagged.

<p style="text-align: right;">Page 66</p> <p>1 Q. Okay.</p> <p>2 A. And so I'd say anything maybe</p> <p>3 other than -- a condition other than what we</p> <p>4 would expect to see, but I'm not sure what</p> <p>5 the details were.</p> <p>6 Q. So can you describe what any</p> <p>7 red flags would be?</p> <p>8 A. No, I'm not an expert.</p> <p>9 Q. Were you involved in helping</p> <p>10 Mallinckrodt identify any suspicious orders?</p> <p>11 A. No.</p> <p>12 Q. Were you on the Suspicious</p> <p>13 Order Monitoring team?</p> <p>14 A. No.</p> <p>15 Q. And you said earlier</p> <p>16 Mallinckrodt had an SOM team, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Do you recall when it was</p> <p>19 formed?</p> <p>20 A. No.</p> <p>21 Q. So is it your testimony that</p> <p>22 you were not involved in the SOM team in any</p> <p>23 way?</p> <p>24 A. Oh, that's not my testimony.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 68</p> <p>1 in his role for quite a while, and I felt</p> <p>2 like it was time for him to have a challenge.</p> <p>3 And at the same time, I think,</p> <p>4 you know, I kind of like people</p> <p>5 cross-functional and doing that stuff.</p> <p>6 Q. So was it your perception that</p> <p>7 managing dosage was more difficult than</p> <p>8 managing API or bulk?</p> <p>9 A. No.</p> <p>10 Q. Just a different experience?</p> <p>11 A. Exactly.</p> <p>12 Q. Okay. Are you familiar with</p> <p>13 the term "do not ship list"?</p> <p>14 A. Yes.</p> <p>15 Q. And what is that?</p> <p>16 A. I can't recall, like,</p> <p>17 specifically like what it was, but I know we</p> <p>18 had a do not ship list which, at the agent</p> <p>19 level, they would check orders or, I guess,</p> <p>20 customers against.</p> <p>21 Q. So what is your understanding</p> <p>22 of the purpose of the do not ship list?</p> <p>23 A. Not to -- not to ship to those</p> <p>24 customers.</p> <p>25 Q. And how did an entity end up on</p>
<p style="text-align: right;">Page 67</p> <p>1 A. I was not a member of the team.</p> <p>2 Q. Were you involved in the SOM</p> <p>3 team in any way?</p> <p>4 A. Yes.</p> <p>5 Q. How so?</p> <p>6 A. I had some direct reports who</p> <p>7 were on the team.</p> <p>8 Q. And who were your direct</p> <p>9 reports that were on the team?</p> <p>10 A. Jim Rausch, who is manager of</p> <p>11 API and then later a manager of dosage, and</p> <p>12 Cathy Stewart, who was manager of dosage and</p> <p>13 then later API.</p> <p>14 Q. So did Jim Rausch and Cathy</p> <p>15 Stewart essentially switch positions from API</p> <p>16 to dosage?</p> <p>17 A. Yes.</p> <p>18 Q. And when did that switch occur?</p> <p>19 A. At the time I began my role or</p> <p>20 almost immediately following it, so in 2009.</p> <p>21 Q. Okay. What was the basis for</p> <p>22 that switch?</p> <p>23 A. We were kind of restructuring</p> <p>24 and thinking about where to move talent, and</p> <p>25 I had seen that -- I had learned that Jim was</p>	<p style="text-align: right;">Page 69</p> <p>1 the do not ship list?</p> <p>2 MR. BERG: Object to form.</p> <p>3 A. I'm not sure.</p> <p>4 QUESTIONS BY MS. KEECH:</p> <p>5 Q. Okay.</p> <p>6 (Mallinckrodt-Saffold Exhibit 5</p> <p>7 was marked for identification.)</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. I'm handing you what has been</p> <p>10 marked as Exhibit 5, bearing Bates number</p> <p>11 MNK-T1_000263249.</p> <p>12 (Document review by witness.)</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. Do you recognize this e-mail?</p> <p>15 A. No.</p> <p>16 Q. It's an e-mail sent from Cathy</p> <p>17 Stewart on November 17th, 2009, sent to Karen</p> <p>18 Harper and Jim Rausch, and you were CC'd</p> <p>19 along with Bill Ratliff.</p> <p>20 Do you have any reason to doubt</p> <p>21 the authenticity of this e-mail?</p> <p>22 A. Oh, no.</p> <p>23 Q. Okay. And this e-mail</p> <p>24 indicates that Mallinckrodt was planning to</p> <p>25 have the do not ship list administered by</p>

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1 CDIG. That's the customer data integrity
2 group? Is that correct?
3 A. Yes.
4 Q. And do you know the
5 circumstances as to why Mallinckrodt was
6 transitioning the do not ship list?
7 A. No. It's -- you know, I think
8 Cathy, in this e-mail that I've read, so I
9 can only assume it's stated by Cathy in this
10 e-mail, that those are the reasons why.
11 Q. And Cathy states on the second
12 page of the e-mail: I'd like to eliminate
13 our manual Excel spreadsheet to keep track of
14 these customers. It's a process that lends
15 itself to errors and omissions.
16 Additionally, although good intentioned, I'm
17 concerned that a customer listed on the do
18 not ship list will inadvertently receive
19 product from us.
20 A. Yes.
21 Q. Would you agree with that?
22 MR. BERG: Object to form.
23 A. Certainly I would -- wouldn't
24 dispute it, but I don't really have firsthand
25 knowledge of that, especially in 2009, I

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1 wouldn't have -- I was very new to the group.
2 But I would respect the opinion
3 of Cathy on this.
4 QUESTIONS BY MS. KEECH:
5 Q. Okay. And were you aware that
6 at the time Mallinckrodt was using a manual
7 do not ship list?
8 A. Yes.
9 Q. Okay. And do you know how
10 often the manual spreadsheet was updated?
11 A. No.
12 Q. Okay. Cathy goes on to say:
13 We can then proceed with credit doing a check
14 on the website for physicians that are under
15 investigation and how to handle customers who
16 may have been denied shipments previously but
17 have taken steps to clean house and are now
18 reapproved to do business with us again,
19 perhaps even under the same company name.
20 MR. BERG: I'm sorry, where are
21 you reading that from?
22 MS. KEECH: First page.
23 MR. BERG: Okay. I see it now.
24 Thanks.
25 MS. KEECH: Yep.

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1 QUESTIONS BY MS. KEECH:
2 Q. Were you aware that certain
3 physicians were under investigation at
4 Mallinckrodt or by Mallinckrodt?
5 MR. BERG: Object to form.
6 A. No.
7 QUESTIONS BY MS. KEECH:
8 Q. Do you know what was involved
9 in this reapproval process that Cathy refers
10 to?
11 A. No.
12 Q. Is your understanding, after
13 ready Cathy Stewart's e-mail here, that
14 essentially, if a company was cut off for
15 suspicious orders, provided they passed a
16 subsequent credit check, that Mallinckrodt
17 could then resume providing product to them?
18 MR. BERG: Object to form.
19 A. No, that's not it.
20 QUESTIONS BY MS. KEECH:
21 Q. What is your understanding of
22 the process after a company was cut off for
23 suspicious orders and then wanted to
24 repurchase product from Mallinckrodt?
25 A. I have limited understanding,

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1 but my understanding is that it was our
2 compliance team, along with Bill Ratliff, who
3 is compliance, but security too, and they
4 were the only ones who could make that
5 decision.
6 Q. Okay.
7 (Mallinckrodt-Saffold Exhibit 6
8 was marked for identification.)
9 QUESTIONS BY MS. KEECH:
10 Q. I'm now handing you what has
11 been marked as Exhibit 6 bearing Mallinckrodt
12 Bates number MNK-T1_0000302469.
13 Do you recognize this document?
14 A. Yes.
15 Q. And what is it?
16 A. It's just -- it's an e-mail
17 from me to my direct report asking him to
18 update his goals.
19 Q. And can you read aloud the
20 stated goal?
21 A. "Ensure compliance with
22 regulatory and internal governance
23 requirements by completing assigned SOX
24 testing before the end of March 2010, by
25 establishing and implementing the procedures

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1 required to support Suspicious Order
2 Monitoring, and by completing SOPs on the
3 order management of controlled substances
4 before the end of Q2."

5 Q. Thank you.

6 And you indicated that this was
7 a goal that you were trying to add. What
8 were you trying to add this to?

9 MR. BERG: Object to form.

10 A. To -- we have a system, right,
11 where we put goals in there, and I was trying
12 to get it into Jim's goals in that system.

13 QUESTIONS BY MS. KEECH:

14 Q. Okay. And was this a goal that
15 you generated for him?

16 A. It's a goal we agreed upon.

17 Q. Okay. And what is S-O-X or SOX
18 testing?

19 A. Sarbanes-Oxley.

20 Q. Okay. And can you describe
21 that?

22 A. Sure.

23 So Sarbanes-Oxley is financial
24 controls by reg- -- by law. So one of our
25 requirements in our group was to look at --

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1 was to test to make sure that we had the
2 proper financial controls in place, and
3 that's to what that referred.

4 (Mallinckrodt-Saffold Exhibit 7
5 was marked for identification.)

6 QUESTIONS BY MS. KEECH:

7 Q. I'm now handing you what has
8 been marked as Exhibit 7, bearing Bates
9 number MNK-T1_0000303789.

10 Do you recognize this?

11 A. No.

12 Q. What is this document?

13 MR. BERG: Object to form.

14 A. Well, I don't know. It looks
15 like it was an automatic e-mail that
16 resulted -- that was a result of maybe the
17 goal getting updated, but that's a guess.

18 QUESTIONS BY MS. KEECH:

19 Q. Okay. It does say that you're
20 on -- that you were the sender of this
21 document.

22 MR. BERG: Object to form.

23 QUESTIONS BY MS. KEECH:

24 Q. Is that correct, according to
25 the document?

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1 A. It does say this is an
2 automated e-mail. Please do not reply to
3 this e-mail address. So I don't know if it
4 just used that almost -- my name as almost
5 like an alias. So I don't know.

6 Q. This e-mail indicates that Jim
7 Rausch's individual goal was approved.

8 A. Yes.

9 Q. Is that consistent with your
10 recollection?

11 A. Yes.

12 Q. Okay. And was Jim Rausch's
13 compensation tied to his goal?

14 A. Yes.

15 Q. Do you know whether he
16 accomplished his goal?

17 MR. BERG: Object to form.

18 A. I can't recall.

19 QUESTIONS BY MS. KEECH:

20 Q. Can you tell me more about how
21 his compensation was tied to his goal?

22 A. Yes. So each member of my team
23 during this time period would have a handful
24 of goals, and then based on their rating for
25 each goal, that would roll up to an overall

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1 rating.

2 And then the amount of merit
3 increase I would give to -- not really I
4 would give, but amount of merit increase
5 would be kind of based on their performance
6 rating in addition to other factors like
7 where they were in the market and how much
8 they're currently making.

9 Q. Okay. So were you familiar
10 with the Suspicious Order Monitoring program?

11 MR. BERG: Object to form.

12 A. I was -- I would say no. I was
13 familiar with, you know, our support of the
14 Suspicious Order Monitoring program, but not
15 the program itself.

16 QUESTIONS BY MS. KEECH:

17 Q. Okay. But you oversaw Jim
18 Rausch, who was working on that?

19 A. Yes. Jim Rausch was working on
20 the dosage customer service piece of the
21 Suspicious Order Monitoring program, with our
22 compliance group.

23 Q. Thank you.

24 (Mallinckrodt-Saffold Exhibit 8
25 was marked for identification.)

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1 QUESTIONS BY MS. KEECH:
 2 Q. I'm handing you what has been
 3 marked as Exhibit 8, bearing Bates number
 4 MNK-T1_000263201. This is an e-mail from
 5 Karen Harper to Cathy Stewart sent on
 6 January 19th, 2001.
 7 And in this correspondence,
 8 Karen e-mails Cathy Stewart following up on
 9 an e-mail indicating that they turn off the
 10 30-day cumulative increase trigger until
 11 George resolves and asking if George
 12 mentioned anything about having gotten
 13 feedback on how to fix the formula.
 14 MR. BERG: Object to form.
 15 QUESTIONS BY MS. KEECH:
 16 Q. In this e-mail, do you know
 17 whether they were referring to you?
 18 MR. BERG: Object to form.
 19 A. No.
 20 QUESTIONS BY MS. KEECH:
 21 Q. Was there any other George that
 22 worked with you in Mallinckrodt?
 23 A. That worked with me? I mean,
 24 yeah, there were other people named George at
 25 Mallinckrodt.

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1 Q. Any in customer service?
 2 A. Not that I recall.
 3 Q. Okay. Are you familiar with
 4 the term "30-day cumulative increase
 5 trigger"?
 6 A. No.
 7 Q. Were you at all involved in the
 8 formula involved in the Suspicious Order
 9 Monitoring program?
 10 MR. BERG: Object to form.
 11 A. No.
 12 QUESTIONS BY MS. KEECH:
 13 Q. Do you know who Mansfield is?
 14 A. Mansfield is a town in
 15 Massachusetts where Covidien had offices.
 16 Q. Okay. You can set that aside.
 17 (Mallinckrodt-Saffold Exhibit 9
 18 was marked for identification.)
 19 QUESTIONS BY MS. KEECH:
 20 Q. I'm handing you what has been
 21 marked as Exhibit 9, bearing Bates number
 22 MNK-T1_000496062.
 23 Do you recognize this document?
 24 A. No.
 25 Q. Any reason to doubt its

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1 authenticity?
 2 A. No.
 3 Q. This is a Suspicious Order
 4 Monitoring team charter indicating that the
 5 team started on March 28, 2008. Is that
 6 correct?
 7 MR. BERG: Object to form.
 8 A. Yes.
 9 QUESTIONS BY MS. KEECH:
 10 Q. Okay. And this charter
 11 indicates that you were on the SOM steering
 12 committee.
 13 A. Yes.
 14 Q. And that you attended meetings
 15 once per quarter. Is that correct?
 16 MR. BERG: Object to form.
 17 A. Yes.
 18 QUESTIONS BY MS. KEECH:
 19 Q. Okay. So --
 20 A. I'm sorry. It indicates that
 21 there were steering committee meetings with a
 22 frequency of once per quarter and that I was
 23 a member of the steering committee. It
 24 doesn't really give any kind of indication
 25 whether I was in attendance.

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1 Q. Okay. Did you attend meetings
 2 for this Suspicious Order Monitoring team?
 3 A. I believe so. I don't recall
 4 like a specific meeting, but...
 5 Q. Did you receive communications
 6 regarding the Suspicious Order Monitoring
 7 team?
 8 A. Yes.
 9 Q. Did you participate in any way?
 10 A. No.
 11 Q. So how would you describe your
 12 role as a steering committee member?
 13 A. I really can't recall doing
 14 much as a steering committee member, so I
 15 would say it was peripheral.
 16 Q. Were you familiar with the
 17 process description of the Suspicious Order
 18 Monitoring team?
 19 MR. BERG: Object to form.
 20 A. Yes.
 21 QUESTIONS BY MS. KEECH:
 22 Q. Can you read the process
 23 description on this document?
 24 A. "Maintain regulatory compliance
 25 with DEA mandated Suspicious Order Monitoring

<p style="text-align: right;">Page 82</p> <p>1 (SOM) as stated in 21 C.F.R. 1301.74(b). 2 Upgrade Mallinckrodt's existing SOM program 3 to meet/exceed DEA requirements and to adapt 4 program based upon changing trends in 5 diversion and abuse of controlled 6 substances." 7 Q. Thank you. 8 So as a steering committee 9 member, were you aware of the DEA 10 requirements for developing an SOM? 11 A. No. And -- no. 12 (Mallinckrodt-Saffold 13 Exhibit 10 was marked for 14 identification.) 15 QUESTIONS BY MS. KEECH: 16 Q. I'm now handing you what has 17 been marked as Exhibit 10, bearing Bates 18 number MNK-T1_000496098. 19 A. Thank you. 20 Q. And this document is the 21 Mallinckrodt Controlled Substance Suspicious 22 Order Monitoring Program, Presentation for 23 Marketing Group dated March 21st, 2011. 24 Are you familiar with this 25 document?</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. And Karen Harper was the team 2 leader? Is that correct? 3 A. Yes. 4 Q. What was your working 5 relationship with Karen Harper, if any? 6 A. So we were colleagues. 7 Q. Okay. 8 A. At times, we did report to the 9 same boss, and really, my relationship with 10 Karen was what Karen says we need to do, we 11 need to do, right. So we listen to Karen. 12 Q. And Jim Rausch was your direct 13 report, correct? 14 A. Yes. 15 Q. Okay. Do you know who 16 generated this PowerPoint? 17 A. No. 18 Q. Can you please turn your 19 attention to page 2 of the PowerPoint. This 20 is difficult to read. It's difficult to see 21 on the paper, but I can represent to you that 22 it reads: Perry Moore, the executive 23 producer of the Chronicles of Narnia movies, 24 was found dead in his New York apartment 25 Thursday, February 17th, 2011, after an</p>
<p style="text-align: right;">Page 83</p> <p>1 A. No. 2 Q. Any reason to doubt its 3 authenticity? 4 A. No. 5 Q. Can you please turn with me to 6 page 4 of the document. 7 A. Sure. 8 Q. This lists you and Jim Rausch 9 as the SOM representatives from the customer 10 service department, correct? 11 A. I think it lists us as members 12 of the procedure team. 13 Q. And were you a member of the 14 procedure team? 15 A. Yes. 16 Q. Okay. Did you have any other 17 roles on the SOM team? 18 A. Not that I can recall. 19 Q. Can you describe your role as a 20 member of the procedure team? 21 A. I really don't recall what I 22 did as a member of the procedure team. 23 Q. Do you know how team members 24 were selected? 25 A. No.</p>	<p style="text-align: right;">Page 85</p> <p>1 apparent overdose, reports the New York Daily 2 News. 3 The 39-year-old producer was 4 found in the bathroom around 9:30 a.m. by 5 partner Hunter Hill. Moore's father, Bill, 6 tells the Daily News, "We're in shock. He 7 was in a great, great mood when we spoke with 8 him the night before. No one was expecting 9 this." 10 Were you aware that people were 11 dying from prescription drug overdoses? 12 MR. BERG: Object to form. 13 A. Yes. 14 QUESTIONS BY MS. KEECH: 15 Q. Okay. And please turn with me 16 to page 6 of this document. And this 17 addresses DEA policy on suspicious orders. 18 Were you aware of these 19 requirements? 20 MR. BERG: Object to form. 21 A. Yes. 22 QUESTIONS BY MS. KEECH: 23 Q. So you were aware of 24 Mallinckrodt's obligations to design and 25 operate a Suspicious Order Monitoring system?</p>

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1 MR. BERG: Object to form.
2 A. Yes.
3 QUESTIONS BY MS. KEECH:
4 Q. Okay. Can you turn with me to
5 page 8. This contains an image of a 2007
6 letter sent from the DEA.
7 Do you recognize this letter?
8 MR. BERG: Object to form.
9 A. No.
10 QUESTIONS BY MS. KEECH:
11 Q. Never seen it before?
12 A. I wouldn't say I've never seen
13 it before. I certainly don't recognize it,
14 and I guess I'd point out that I'm just
15 looking at the date of this letter and it was
16 certainly prior to me even working in any
17 controlled substances at Mallinckrodt.
18 Q. Okay. But when you began
19 working in customer service in 2009, did
20 anyone discuss this letter with you?
21 A. I think as part of the
22 training, you know, the requirements that the
23 letter seemed to indicate, yes.
24 Q. Okay.
25 A. So I wouldn't -- but I can't

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1 really recall discussing this letter.
2 Q. Do you recall whether your
3 training discussed whether Mallinckrodt was
4 required to inform the local DEA diversion
5 office of suspicious orders when they were
6 discovered?
7 A. Yes.
8 Q. And were you aware that the DEA
9 could immediately suspend or revoke
10 registration for violations of the Controlled
11 Substances Act?
12 A. Yes.
13 Q. Were you aware of distributors
14 who got into trouble with the DEA?
15 MR. BERG: Object to form.
16 A. Yes.
17 QUESTIONS BY MS. KEECH:
18 Q. Okay. So please turn with me
19 to page 9. This indicates the DEA suspends
20 the licenses of distributors for not
21 maintaining effective controls -- effective
22 controls against diversion of controlled
23 substances, and then it lists three
24 distributors.
25 A. Uh-huh.

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1 Q. Are you familiar with those?
2 MR. BERG: Object to form.
3 A. Am I familiar with the
4 distributors?
5 QUESTIONS BY MS. KEECH:
6 Q. Correct.
7 A. Yes.
8 Q. And were you aware of each of
9 these disciplinary actions against them?
10 A. Yes, in terms of I've seen kind
11 of this slide in my training, but no in terms
12 of like what was -- you know, any details.
13 Q. So turning to page 15, this
14 references the DEA's St. Louis conversation
15 from July 20th, 2010. The third line down
16 indicates Mallinckrodt is viewed as the
17 kingpin within the drug cartel.
18 What does that mean to you?
19 MR. BERG: Object to form.
20 A. I don't know. I don't recall
21 ever hearing or anything intimated like that
22 before.
23 QUESTIONS BY MS. KEECH:
24 Q. Is this the first time that
25 you've heard Mallinckrodt referred to as the

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1 kingpin within the drug cartel?
2 A. Yes.
3 Q. Okay. Would you agree with
4 that characterization?
5 A. No.
6 Q. If you'll turn with me to
7 page 17, this image appears to be a
8 photograph taken from inside of a vehicle of
9 individuals lined up outside.
10 Are you familiar with this
11 photo?
12 A. I don't recall. I don't
13 think -- I'm not familiar with it, no.
14 Q. Do you know what this photo
15 represents --
16 MR. BERG: Object to form.
17 A. No.
18 QUESTIONS BY MS. KEECH:
19 Q. -- if anything?
20 Do you know what, if anything,
21 is the significance of this photo?
22 MR. BERG: Object to form.
23 A. No.
24 QUESTIONS BY MS. KEECH:
25 Q. Do you know why it was included

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1 in the PowerPoint?
2 MR. BERG: Object to form.
3 A. No.
4 QUESTIONS BY MS. KEECH:
5 Q. On the next page, 18, there is
6 another image. What does that appear to be
7 of?
8 A. I don't know what this is. It
9 looks like a window with -- I mean, I can
10 only describe the picture. It says, "Leave
11 prescription here," and there's a window and
12 there's signs and there's a sign that says,
13 "No cell phone use in pharmacy," so I'm
14 guessing it's either a window into or out of
15 a pharmacy.
16 Q. And do you see the sign that
17 reads, "We do not accept any insurance on
18 oxycodone products by Mallinckrodt or
19 Actavis"? Lower left.
20 A. I do, yes.
21 Q. Any idea why this photo may
22 have been included in the PowerPoint?
23 MR. BERG: Object to form.
24 A. No.
25 QUESTIONS BY MS. KEECH:

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1 Q. And page 23 of the PowerPoint
2 shows an eBay bid for empty Mallinckrodt
3 bottles. Are you aware of a legitimate
4 reason why someone would want to purchase
5 empty Mallinckrodt bottles?
6 A. No.
7 Q. Do you agree that this
8 advertisement is evidence of diversion or
9 attempted diversion?
10 MR. BERG: Object to form.
11 A. I'm not a diversion person,
12 so...
13 QUESTIONS BY MS. KEECH:
14 Q. Okay. Let's turn back to
15 page 13 of this document. This indicates
16 that it was the existing SOM program prior to
17 June 2010. Take a moment to review this
18 slide.
19 (Document review by witness.)
20 A. Okay.
21 QUESTIONS BY MS. KEECH:
22 Q. Okay. Is this consistent with
23 your understanding of what the SOM program
24 process was prior to June of 2010?
25 MR. BERG: Object to form.

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1 A. Yes.
2 QUESTIONS BY MS. KEECH:
3 Q. Okay. And after or sometime
4 during 2010, the -- did the SOM program
5 change?
6 A. I don't remember.
7 Q. Do you remember whether it
8 changed?
9 A. Yes. I mean, there were
10 changes.
11 Q. Okay.
12 A. You know, the timing of
13 changes, kind of a constant, continuous
14 improvement process, so I'm not sure -- you
15 know, I couldn't really be assigned any time
16 frame for a particular change nor, you know,
17 characterize any change.
18 Q. Okay. Are you aware of whether
19 there was ever a shift away from the customer
20 service manager reviewing orders in the new
21 SOM program?
22 A. Yes.
23 Q. Okay. And do you know when
24 that occurred?
25 A. No.

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1 Q. Do you know why there was a
2 shift from customer service reviewing orders?
3 A. No.
4 Q. Were you aware of whether there
5 was ever any concern expressed by the DEA
6 regarding a potential conflict of interest in
7 customer service regulating but having a
8 conflicting interest?
9 MR. BERG: Object to form.
10 A. No.
11 QUESTIONS BY MS. KEECH:
12 Q. Do you personally believe there
13 is a conflict of interest in being involved
14 in customer service and also having customer
15 service regulate suspicious orders?
16 MR. BERG: Object to form.
17 A. No, absolutely not. So to give
18 service, there's no service without
19 compliance. So it was in our interest to
20 comply.
21 MR. BERG: How you doing? Do
22 you want to take a quick break?
23 THE WITNESS: Yeah, why don't
24 we take a break.
25 MR. BERG: Is that okay?

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1 MS. KEECH: Sure. Yeah, that's
2 fine.
3 THE VIDEOGRAPHER: Off the
4 record at 11:14.
5 (Recess taken, 11:14 a.m. to
6 11:27?a.m.)
7 THE VIDEOGRAPHER: All right,
8 stand by. The time is 11:27. Back on
9 the record, beginning of File 2.
10 QUESTIONS BY MS. KEECH:
11 Q. Are you aware of whether
12 Mallinckrodt ever sold empty pill bottles?
13 A. No.
14 Q. Do you recall anyone ever
15 discussing why having empty pill bottles on
16 the market would be problematic?
17 MR. BERG: Object to form.
18 A. No.
19 QUESTIONS BY MS. KEECH:
20 Q. Ever recall any discussion
21 about empty pill bottles in general?
22 A. No.
23 Q. Okay. As part of any of your
24 trainings at Mallinckrodt, do you recall ever
25 watching a presentation that included video

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1 footage of individuals standing outside of a
2 pill mill?
3 A. No.
4 Q. Ever recall hearing about such
5 a video?
6 A. No.
7 Q. Do you remember anyone ever
8 discussing such a video?
9 A. No.
10 Q. Okay.
11 (Mallinckrodt-Saffold
12 Exhibit 11 was marked for
13 identification.)
14 QUESTIONS BY MS. KEECH:
15 Q. I'm handing you what has been
16 marked as Exhibit 11, bearing Bates number
17 MNK-T1_0000303583. This is a Pharmaceutical
18 Logistics Monthly Report dated July 1st,
19 2009, addressed to you from Jim Rausch.
20 Do you recognize this document?
21 A. Yes. Like in terms of like
22 that this is something I required my direct
23 reports to give me.
24 Q. Okay.
25 A. But, you know, I don't recall

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1 the specifics surrounding this specific one,
2 right.
3 Q. Sure.
4 And how many direct reports did
5 you have?
6 A. At the time of -- are you --
7 Q. In 2009.
8 A. In 2009? Jim, Cathy... I'd say
9 six, I believe.
10 Q. Okay. Do you remember who they
11 were?
12 A. Tanisha Hicks, manager of
13 respiratory and monitoring solutions; Jim
14 Rausch, manager of -- I think he was dosage
15 like by July 1, I think he was dosage; Cathy
16 Stewart, manager of API; Charity Aranda was a
17 customer service analyst; Doris Bonds, she
18 was my administrative assistant; and I can't
19 remember, I may have had others, but I can't
20 be sure.
21 Q. Okay. And did you require each
22 of your direct reports, excluding your
23 assistant, to provide you monthly reports?
24 A. Yes.
25 Q. Did you yourself author a

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1 monthly report?
2 A. At this time, yes.
3 Q. Okay. And who did that report
4 go to?
5 A. To my supervisor, so that would
6 have been JoAnne Levy, the VP of logistics at
7 this time.
8 Q. And what was the content of the
9 reports that you authored?
10 A. In a pretty rigid format, so it
11 would have been -- it starts out with HR, and
12 then budget, kind of my head count, and then
13 development, you know, for people and any
14 other personnel highlights and maybe
15 lowlights.
16 Then from there, I usually went
17 into performance on IO, our individual
18 objective performance. So, you know, hey, I
19 know I'm supposed to be doing this, this and
20 this, here's where we are. And then
21 following that was usually like a project, so
22 here's some projects I'm on and here's their
23 status.
24 And then following that, issues
25 or miscellaneous, and that's pretty much my

<p style="text-align: right;">Page 98</p> <p>1 format I've always used.</p> <p>2 Q. Do you know whether your</p> <p>3 monthly reports were ever submitted to the</p> <p>4 DEA?</p> <p>5 A. No.</p> <p>6 Q. Did customer service, in</p> <p>7 general, submit monthly reports to anyone?</p> <p>8 MR. BERG: Object to form.</p> <p>9 A. I'm sorry. Can you repeat that</p> <p>10 question?</p> <p>11 QUESTIONS BY MS. KEECH:</p> <p>12 Q. Sure.</p> <p>13 Did customer service, in</p> <p>14 general, submit a monthly report</p> <p>15 summarizing --</p> <p>16 MR. BERG: Object to form.</p> <p>17 A. To anyone?</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. To anyone.</p> <p>20 A. No. Not like an overall</p> <p>21 customer service report, no.</p> <p>22 Q. Okay. Do you know whether</p> <p>23 Mallinckrodt, in general, submitted monthly</p> <p>24 reports to the DEA?</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 100</p> <p>1 daily suspicious order report, but I'm not</p> <p>2 sure about the specific concern he's talking</p> <p>3 about, right.</p> <p>4 Q. And what was the daily</p> <p>5 suspicious order report?</p> <p>6 A. So I think that's a bit of a</p> <p>7 misnomer in his report. I think there was a</p> <p>8 report that was a peculiar order report, and</p> <p>9 then parameters were set and then the report</p> <p>10 would get generated and Jim was one of the</p> <p>11 recipients of this report. And then he</p> <p>12 worked -- and so that's kind of what it is,</p> <p>13 I guess.</p> <p>14 Q. Okay. And who was the peculiar</p> <p>15 order report sent to?</p> <p>16 A. I'm not sure everyone who it</p> <p>17 was sent to.</p> <p>18 Q. Do you know --</p> <p>19 A. I know Cathy and Jim, I</p> <p>20 believe, both received it.</p> <p>21 Q. Did you ever receive the</p> <p>22 peculiar order report?</p> <p>23 A. I can't recall ever getting it.</p> <p>24 Q. So just to clarify, part of</p> <p>25 your job was to supervise Jim Rausch, who</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. And what was the content of the</p> <p>2 reports that your direct reports generated?</p> <p>3 A. Well, it was a little variable.</p> <p>4 Like if you look at this one, it's not a</p> <p>5 great one, so it's just some personal</p> <p>6 highlights and then some business support</p> <p>7 highlights. And it's just like a lot of</p> <p>8 stuff, right.</p> <p>9 Others might be a little bit</p> <p>10 more on performance or metrics, so it just,</p> <p>11 you know, kind of varied, and as you coached</p> <p>12 people to give you better reports, they would</p> <p>13 give you better ones.</p> <p>14 Q. Okay. So turning to this</p> <p>15 exhibit under API Business Support Highlights</p> <p>16 in the first paragraph, Jim writes: There is</p> <p>17 concern on how time-consuming the daily</p> <p>18 suspicious order report might be for customer</p> <p>19 service to monitor on a daily basis.</p> <p>20 Are you familiar with what he</p> <p>21 was referring to there?</p> <p>22 A. No.</p> <p>23 Q. So you're not aware of what a</p> <p>24 daily suspicious order report was?</p> <p>25 A. So I am familiar with what -- a</p>	<p style="text-align: right;">Page 101</p> <p>1 received the peculiar order reports, correct?</p> <p>2 A. Correct.</p> <p>3 Q. But you never personally</p> <p>4 received the reports?</p> <p>5 MR. BERG: Object to form.</p> <p>6 A. Correct. Or at least I don't</p> <p>7 recall receiving these reports.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. So how were you monitoring</p> <p>10 whether he was in compliance with his stated</p> <p>11 goal with regard to the SOM --</p> <p>12 MR. BERG: Object to form.</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. -- program?</p> <p>15 A. Can you repeat that? How was I</p> <p>16 monitoring what?</p> <p>17 Q. How were you monitoring whether</p> <p>18 Jim was meeting his goals with regard to the</p> <p>19 SOM program if you also -- if you were not</p> <p>20 receiving the suspicious or peculiar order</p> <p>21 reports?</p> <p>22 MR. BERG: Object to form.</p> <p>23 A. Well, I think the primary way</p> <p>24 would be from our compliance team would be</p> <p>25 telling me he's not doing what we need him to</p>

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1 do.
2 QUESTIONS BY MS. KEECH:
3 Q. So you were relying on
4 compliance to tell you whether Jim was
5 satisfying his goals?
6 MR. BERG: Object to form.
7 A. I was relying on compliance to
8 tell me whether or not Jim was satisfying his
9 goals regarding compliance, yes.
10 QUESTIONS BY MS. KEECH:
11 Q. What were other -- Jim's other
12 stated goals outside of compliance?
13 A. I don't know. I don't recall
14 all his goals.
15 Q. Did he have others other than
16 the one that we discussed earlier?
17 A. You know, I don't recall, but
18 it would be safe to say yes.
19 Q. Do you know whether this daily
20 suspicious order report was switched away
21 from customer service?
22 MR. BERG: Object to form.
23 A. I don't know if the report
24 itself was ever switched away from customer
25 service, no, I don't know.

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1 QUESTIONS BY MS. KEECH:
2 Q. So Jim brought up this concern
3 of how time-consuming the daily suspicious
4 order report might be for customer service to
5 monitor on a daily basis.
6 As his supervisor, what, if
7 anything, did you do after receiving this
8 information?
9 A. I can't recall doing anything.
10 I mean, this is -- it's kind of like an FYI.
11 Hey, we're gonna run it, test it and see.
12 Q. And he was expressing that it
13 was time-consuming?
14 A. No, I don't think he was. I
15 think he was expressing that he was concerned
16 it was and he was going to address those
17 concerns by testing it.
18 Q. Okay.
19 A. And so that's it.
20 Q. Do you know what, if anything,
21 the outcome of his testing was?
22 A. No.
23 Q. Please turn with me to the
24 second page, second paragraph, beginning with
25 "Ohm Labs."

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1 It indicates: We missed the
2 ship date on this order a couple of times.
3 A. Okay.
4 Q. It says: We missed the 6/1
5 ship date because label delay, containers
6 were dirtier and more damaged than normal,
7 and there was water coming from the weep
8 holes on the bottom of the containers.
9 Customer service was not notified of this
10 until 6/2, the day after it was supposed to
11 have shipped. Marketing was very upset on
12 this one.
13 Is this the type of information
14 that was shared with customer service?
15 MR. BERG: Object to form.
16 A. Well, I'm not sure I
17 understand, like what type of information --
18 I mean, you're -- this is just an incident
19 that happened.
20 QUESTIONS BY MS. KEECH:
21 Q. Right. So generally speaking,
22 would this type of incident be reported to
23 customer service?
24 A. Yes.
25 Q. Okay. And would customer

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1 service then communicate this type of
2 incident to any other department within
3 Mallinckrodt?
4 A. Yes, or -- but typically when
5 we're finding this out, usually others are
6 aware of it too, sometimes even before us.
7 Yes, so...
8 Q. Okay. And what other groups
9 within Mallinckrodt would customer service
10 share this type of information with?
11 A. Well, certainly the shipping
12 and manufacturing folks, if they weren't
13 aware, the leadership there; planning; sales,
14 you know, the sales rep, I'd think you'd want
15 to let him know; and then marketing,
16 probably.
17 Q. Okay. Was customer service
18 also notified if there was tampering or
19 suspected tampering issues, for example, if
20 product was missing from a container?
21 A. We could be, yes.
22 Q. Okay. And were you ever
23 notified of such tampering issues?
24 A. Yes.
25 Q. How quickly were these

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1 incidents reported within Mallinckrodt?
2 A. Really quickly.
3 Q. Were there ever delays in
4 reporting?
5 A. Not that I recall.
6 Q. Do you recall ever reporting
7 such tampering issues to the DEA?
8 A. No. I typically didn't report
9 anything. But my team, like my -- you know,
10 the first person who hears about this would
11 be a customer service agent, and he or she
12 would then report to a compliance person,
13 really fast, was kind of the goal.
14 Q. Were you CC'd on those
15 communications or copied?
16 A. I don't recall. It's likely I
17 was, but the main vehicle for doing that, I
18 wasn't -- they used like a share file to put
19 the information in.
20 Q. Were there any checks to ensure
21 that customer service agents were in fact
22 reporting these issues to Mallinckrodt
23 compliance?
24 A. I don't know. I would think
25 compliance would be checking that.

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1 Q. Okay. Did customer service
2 agents also identify peculiar orders that
3 then they communicated to compliance?
4 A. I don't believe so.
5 Q. So who at Mallinckrodt, if
6 anyone, was monitoring orders to determine
7 whether they were peculiar or suspicious?
8 A. Well, so my understanding of
9 the Suspicious Order Monitoring program is
10 that the compliance team owns the program and
11 then they set the parameters, which were
12 largely system-driven.
13 Q. What do you mean by that?
14 A. So they set the parameters of
15 like what a definition of a suspicious order
16 would be and then the system could run edits
17 and checks against that and then an order
18 could be flagged as peculiar -- and I don't
19 know if that's the only type of flag -- and
20 then would be able to be investigated.
21 So that monitoring part is
22 really, you know, all orders being reviewed
23 and then, you know, filtered out through this
24 report.
25 Q. You mentioned a 222 form

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1 earlier today. What is a 222 form?
2 A. So not being a compliance
3 expert, and I don't know if I can give you a
4 great definition of it, but in practice, a
5 form -- 222 form would accompany an order,
6 and it demonstrated that one was allowed to
7 purchase the compound or the molecule as well
8 as the quantity.
9 Q. Are you aware whether a 222
10 form was an official form from the DEA?
11 A. Yes, it is an official form.
12 Q. And was it required for every
13 distribution, purchase or transfer of a
14 Schedule II controlled substance?
15 MR. BERG: Object to form.
16 A. No. I'm not a compliance
17 expert, but in addition to a 222 form, the
18 DEA has Controlled Substance Ordering System,
19 sometimes referred to as CSOS, and then those
20 wouldn't have 222 forms because they're
21 electronic and a 222 form is paper.
22 QUESTIONS BY MS. KEECH:
23 Q. Okay. Based on your
24 understanding of a 222 form, is a portion of
25 the form filled out by the purchaser and

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1 another portion filled out by the supplier?
2 A. Yes.
3 Q. Does it include the drug code,
4 supplier's DEA registration number and the
5 number of packages shipped and the date of
6 shipment?
7 MR. BERG: Object to form.
8 A. I don't think I could tell you
9 exactly what's on the form.
10 QUESTIONS BY MS. KEECH:
11 Q. Okay.
12 (Mallinckrodt-Saffold
13 Exhibit 12 was marked for
14 identification.)
15 QUESTIONS BY MS. KEECH:
16 Q. I'm handing you what has been
17 marked as Exhibit 12. This is bearing Bates
18 number MNK-T1_0000302318.
19 Do you recognize this document?
20 A. Yes.
21 Q. And what is it?
22 A. This is a monthly report
23 written by me.
24 Q. To your supervisor, JoAnne
25 Levy?

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1 A. Yes.

2 Q. And is this the type of report

3 that we discussed earlier that you generated

4 on a monthly basis?

5 A. Yes.

6 Q. Okay. If you'll turn with me

7 to the last page of the report, under the

8 heading Specialty Pharmaceutical Products,

9 you wrote that the time to clear 222 forms

10 was improved from several days to 1 day.

11 Can you describe the process

12 for me involved in clearing a 222 form?

13 A. Not with any confidence.

14 Q. So who was responsible for

15 clearing 222 forms?

16 A. Customer service agents.

17 Q. So as their supervisor, you did

18 not know what customer service agents did to

19 clear 222 forms?

20 MR. BERG: Object to form.

21 A. Not at the level to be able to

22 describe the process.

23 QUESTIONS BY MS. KEECH:

24 Q. Okay. Can you describe the

25 purpose?

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1 A. Yes. The purpose of clearing a

2 222 form was to report the sale and track the

3 sale.

4 Q. So any idea of what occurred

5 when someone was clearing a 222 form?

6 A. Not like specifically. So they

7 would, you know, work the form after an order

8 shipped and make sure that things -- you

9 know, the fields were indicated, right, and

10 they would take the forms and make sure those

11 went to our DEA compliance team for record

12 retention. And I think -- I don't know what

13 our compliance team did with them afterwards.

14 Q. So this indicates the process

15 previously took several days, and then

16 indicates that it was shifted to one day.

17 A. Yes.

18 Q. Was there an emphasis placed on

19 timing or completing these forms?

20 A. I'm not sure. I don't really

21 recall.

22 Q. Did anyone at Mallinckrodt

23 emphasize ensuring that the forms are

24 properly filled out?

25 A. Yes.

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1 Q. And who was responsible for

2 that?

3 A. Well, I'm sorry, who was

4 responsible for making sure the forms were

5 filled out? So the customer service agents

6 had to fill them out and then the compliance

7 team was the ones who really made sure they

8 were perfect.

9 Q. Are you aware of any errors

10 ever being on DEA 222 forms at Mallinckrodt?

11 A. Yes.

12 Q. And do you know whether all of

13 those were reported to the DEA?

14 MR. BERG: Object to form.

15 A. I'm not sure. I'm -- you know,

16 any error I was ever made aware of,

17 absolutely, yes.

18 QUESTIONS BY MS. KEECH:

19 Q. Okay.

20 (Mallinckrodt-Saffold

21 Exhibit 13 was marked for

22 identification.)

23 QUESTIONS BY MS. KEECH:

24 Q. I'm handing you what's been

25 marked as Exhibit 13, bearing Bates stamp

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1 MNK-T1_000280653.

2 Do you recognize this document?

3 A. Yes.

4 Q. And what is it?

5 A. It's a monthly report.

6 Q. Similar to the report we just

7 discussed?

8 A. Yes.

9 Q. Okay. And this time it was

10 sent to Mike Santowski. Is that correct?

11 A. Yes.

12 Q. Who was Mike Santowski?

13 A. He was my supervisor on that

14 date.

15 Q. Okay. And this was dated

16 November 2nd, 2010, reporting on October

17 monthly sales from 2010? Is that correct?

18 A. No, it wasn't reporting on

19 October monthly sales.

20 Q. Or, excuse me. October monthly

21 report.

22 A. Yes.

23 Q. Okay. And under the heading

24 Specialty Generics and Specialty Brands, you

25 indicate that the peculiar order monitoring

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1 report and process will be moved from
2 customer service to compliance this week.
3 MR. BERG: Object to form.
4 QUESTIONS BY MS. KEECH:
5 Q. Do you recall that?
6 A. No. Like -- no. Like any of
7 the circumstances around it, no.
8 Q. Do you recall that that
9 occurred?
10 A. Yes.
11 Q. Okay. Any reason to doubt that
12 you didn't write that?
13 A. No, I'm pretty sure I did.
14 Q. Do you recall why customer
15 service was shifting responsibility to
16 compliance for the peculiar order monitoring
17 report?
18 A. No. And I guess maybe the
19 characterization that customer service was
20 shifting responsibility to compliance might
21 not be accurate. I would say more
22 compliance, you know, gets to say how we
23 comply, and compliance was saying, eh, we're
24 going to take this over. That's a more fair
25 characterization.

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1 Q. Okay. Do you know why
2 compliance made the decision to take over the
3 peculiar order monitoring?
4 A. No.
5 Q. Do you have any information
6 about the background behind that decision?
7 A. I can't recall any.
8 Q. Do you recall whose idea it
9 was?
10 A. I really can't recall any
11 information.
12 Q. Okay.
13 (Mallinckrodt-Saffold
14 Exhibit 14 was marked for
15 identification.)
16 QUESTIONS BY MS. KEECH:
17 Q. I'm now handing you what's been
18 marked as Exhibit 14, bearing Bates number
19 MNK-T1_000269705.
20 And you were on the SOM
21 steering committee, correct?
22 A. Yes.
23 Q. Did compliance ever consult
24 with you about orders that had been flagged
25 as potentially suspicious or peculiar?

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1 A. I can't recall any instance.
2 Q. Do you know or can you describe
3 how Mallinckrodt would determine whether an
4 order flagged as peculiar should be shipped?
5 MR. BERG: Object to form.
6 A. I'm not really familiar with
7 the details at all on how that would occur.
8 QUESTIONS BY MS. KEECH:
9 Q. Okay. Did you ever have any
10 communications with customers that raised any
11 red flags to you about potential abuse or
12 diversion?
13 A. No.
14 Q. And prior to 2011, did you ever
15 recommend that an order be cancelled because
16 you believed it was peculiar or suspicious?
17 A. I don't think so, no.
18 Q. How about after 2011?
19 A. I don't think so either.
20 Q. Okay. So in Exhibit 14, this
21 indicates that in March of 2010, you met with
22 Cathy Stewart, Jim Rausch and Karen Harper to
23 fine-tune the SOM algorithm.
24 A. Uh-huh.
25 Q. Do you recall that meeting?

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1 A. No.
2 Q. Do you recall working on the
3 SOM algorithm?
4 A. No.
5 Q. Do you know what the SOM
6 algorithm was?
7 A. No. I mean, so, yes, it was an
8 algorithm used to look at orders to help
9 comply with Suspicious Order Monitoring.
10 Q. But no recollection of working
11 on that?
12 A. No.
13 Q. Did you participate at all in
14 generating the reports that were sent to the
15 DEA?
16 A. No.
17 Q. Did you ever see any reports
18 that were sent to the DEA?
19 A. None that I can recall. I'm
20 pretty sure no.
21 Q. Okay.
22 (Mallinckrodt-Saffold
23 Exhibit 15 was marked for
24 identification.)
25 --oOo--

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1 QUESTIONS BY MS. KEECH:
2 Q. I'm handing you what has been
3 marked as Exhibit 15, bearing Bates number
4 MNK-T1_0000262762. This is an e-mail sent
5 from Jim Rausch to Karen Harper, you were
6 CC'd, on Wednesday, June 9th, 2010, subject
7 line: Suspicious Order Monitoring program.
8 Do you recall receiving this
9 e-mail?
10 A. No.
11 Q. Any reason to doubt its
12 authenticity?
13 A. No.
14 Q. Okay. And in this e-mail, Jim
15 Rausch indicates he's not had any orders in
16 the classification of peculiar that have not
17 been cleared and explainable thus far.
18 Are you familiar with the term
19 "peculiar order"?
20 MR. BERG: Object to form.
21 A. Yes, somewhat.
22 QUESTIONS BY MS. KEECH:
23 Q. Okay. And how would you define
24 "peculiar order"?
25 MR. BERG: Object to form.

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1 A. So I'm not sure I can define
2 it. I'm familiar in that orders that were
3 flagged -- were flagged as peculiar based on
4 criteria set by our Suspicious Order
5 Monitoring people in compliance.
6 QUESTIONS BY MS. KEECH:
7 Q. Okay. Do you know what that
8 criteria was?
9 MR. BERG: Object to form.
10 A. No. And I don't know if it
11 ever -- you know, I think it may have changed
12 over a period of time as well, so...
13 QUESTIONS BY MS. KEECH:
14 Q. Are you familiar with how the
15 term "peculiar order" differed from a
16 suspicious order?
17 MR. BERG: Object to form.
18 A. No.
19 QUESTIONS BY MS. KEECH:
20 Q. So who had the authority within
21 Mallinckrodt to determine whether a peculiar
22 order, or order that was identified as either
23 peculiar or suspicious, was okay to ship?
24 MR. BERG: Object to form.
25 A. Compliance.

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1 QUESTIONS BY MS. KEECH:
2 Q. Okay. Do you know who within
3 compliance had that role?
4 A. No.
5 Q. Okay. Do you see, in the first
6 paragraph here, where Jim also writes: Since
7 I don't hold the orders up during my due
8 diligence, it's possible that the order could
9 ship?
10 A. Yes.
11 Q. Were you familiar with this
12 practice?
13 A. Yes.
14 Q. Okay. And did you find it
15 problematic at all of shipping prior to Jim
16 doing his due diligence?
17 A. I really am not compliance,
18 right, so if Karen or anyone in compliance
19 had said it's problematic, then it would be,
20 if they're aware of it, and then I don't find
21 it problematic at all.
22 Q. So you just deferred to Karen
23 in compliance?
24 A. Yes.
25 Q. Did you ever see orders that

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1 you believed that were peculiar that were
2 ultimately shipped?
3 A. I never -- no, I can't really
4 recall seeing any peculiar orders.
5 Q. Were you reviewing the peculiar
6 order reports?
7 MR. BERG: Object to form.
8 A. I did not review peculiar order
9 reports.
10 (Mallinckrodt-Saffold
11 Exhibit 16 was marked for
12 identification.)
13 QUESTIONS BY MS. KEECH:
14 Q. Okay. I'm handing you what has
15 been marked as Exhibit 16, bearing Bates
16 MNK-T1_0000268194.
17 (Document review by witness.)
18 QUESTIONS BY MS. KEECH:
19 Q. Are you familiar with this
20 document?
21 A. No.
22 Q. Okay. This is dated July 30th,
23 2010, from Tiffany Kilper Rowley, subject:
24 DEA Suspicious Order Monitoring program, and
25 your name is listed as one of the required

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1 attendees.
2 Do you recall attending this
3 meeting?
4 A. No.
5 Q. Okay. If you'll turn your
6 attention to the handwritten note at the
7 bottom of this e-mail, it reads: 99% orders
8 legit so do not hold orders.
9 Were you aware that orders were
10 not being held?
11 MR. BERG: Object to form.
12 QUESTIONS BY MS. KEECH:
13 Q. Before a due diligence was
14 completed?
15 MR. BERG: Object to form.
16 A. So I think that's an
17 overstatement. Orders could go on hold,
18 so -- for a number of reasons. So -- so I'm
19 not sure.
20 QUESTIONS BY MS. KEECH:
21 Q. So Mallinckrodt had the
22 capacity to put orders on hold. Is that
23 correct?
24 A. Yes.
25 Q. Okay. But as Jim indicated in

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1 his prior e-mail, he did not personally hold
2 orders up during his due diligence.
3 MR. BERG: Object to form.
4 A. Yes.
5 QUESTIONS BY MS. KEECH:
6 Q. Okay. So if the stated goal of
7 the SOM team is to meet or exceed DEA
8 expectations, do you believe that this
9 practice is consistent with the DEA
10 requirements in the stated goals of the SOM
11 charter to not complete due diligence before
12 shipping an order?
13 MR. BERG: Object to form.
14 A. I'm not a compliance expert,
15 right, so I'm not sure exactly what the
16 requirements from the DEA were and wouldn't
17 have a good informed opinion on how well it
18 met or exceeded.
19 QUESTIONS BY MS. KEECH:
20 Q. Well, as a supervisor of an
21 employee whose job was to ensure that orders
22 were not shipped that were peculiar, does it
23 strike you as problematic that orders are
24 being shipped prior to the due diligence
25 being completed?

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1 MR. BERG: Object to form.
2 A. I'm not sure Jim's job was to
3 ensure orders were not shipped prior to due
4 diligence being performed.
5 QUESTIONS BY MS. KEECH:
6 Q. How would you describe Jim's
7 job?
8 A. Jim was supervising the
9 customer service team, so he had, you know,
10 to manage his employees and then also, you
11 know, perform any other activities as
12 required, right.
13 (Mallinckrodt-Saffold
14 Exhibit 17 was marked for
15 identification.)
16 QUESTIONS BY MS. KEECH:
17 Q. I'm handing you what has been
18 marked as Exhibit 17, bearing Bates
19 MNK-T1_0000262763. This is an e-mail dated
20 June 9th, 2010, from Jim Rausch to Karen
21 Harper with a CC to you regarding Suspicious
22 Order Monitoring program.
23 Do you recognize this document?
24 A. No.
25 Q. Any reason to doubt its

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1 authenticity?
2 A. No.
3 Q. Okay. And here, Jim writes to
4 Karen: As we discussed, I do not hold any
5 orders while I do my research due to the time
6 constraints.
7 Are you aware of whether
8 Mallinckrodt ever asked a company to return
9 an order that had been shipped?
10 A. Yes, I am aware we've asked
11 customers to return orders that have been
12 shipped.
13 Q. Okay. And when you left
14 Mallinckrodt, was it still Mallinckrodt's
15 practice to ship, then investigate or
16 complete the investigation of orders?
17 MR. BERG: Object to form.
18 A. I don't know.
19 MS. KEECH: Okay. It's my
20 understanding that the lunch is here.
21 Do folks want to take a break now?
22 MR. BERG: Sure.
23 MS. KEECH: Or should we keep
24 going?
25 MR. BERG: Up to you. I don't

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1 know how you're feeling.
2 THE WITNESS: You want to maybe
3 go like 10 or 15 more minutes?
4 MR. BERG: 12:30?
5 MS. KEECH: Sure, that's fine.
6 Okay, we'll go till 12:30.
7 (Mallinckrodt-Saffold
8 Exhibit 18 was marked for
9 identification.)
10 QUESTIONS BY MS. KEECH:
11 Q. Okay. I'm handing you what has
12 been marked Exhibit 18, bearing Bates number
13 MNK-T1_0280678.
14 Do you recognize this document?
15 A. No.
16 Q. Okay. What is it?
17 A. It looks like either an e-mail
18 or a decline, you know, from a calendar
19 request from me to Karen on the 3rd of
20 November 2010, letting her know I won't be
21 able to make the meeting next week but I'm
22 comfortable with our progress and the
23 direction so far.
24 Q. Okay. And what progress were
25 you referring to?

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1 A. I don't recall.
2 Q. Do you recall what progress in
3 general the SOM team made from its inception
4 to November of 2010?
5 A. No.
6 Q. You noted that you were
7 "comfortable with our progress and direction
8 so far."
9 Was there ever a time that you
10 were uncomfortable with the direction or
11 progress of the SOM team?
12 A. No.
13 Q. Were you ever uncomfortable
14 with decisions made regarding whether to
15 report an order or a circumstance to the DEA?
16 A. No.
17 Q. Did you ever disagree with
18 decisions that were made with respect to
19 Suspicious Order Monitoring?
20 A. Not that I can recall, and I
21 don't think I was privy to a lot of decisions
22 being made.
23 Q. So you were invited to the
24 meetings and invited to participate on the
25 algorithm but weren't privy to decisions of

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1 the SOM team?
2 MR. BERG: Object to form.
3 A. I said I can't really recall,
4 you know, like a specific decision.
5 QUESTIONS BY MS. KEECH:
6 Q. But generally speaking, did you
7 have access to the agendas and information of
8 the SOM team and projects that they were
9 working on?
10 A. Yes.
11 Q. Okay.
12 (Mallinckrodt-Saffold
13 Exhibit 19 was marked for
14 identification.)
15 QUESTIONS BY MS. KEECH:
16 Q. I'm handing you what's been
17 marked as Exhibit 19, bearing Bates
18 MNK-T1_0000301254.
19 A. Thank you.
20 Q. Do you recognize this document?
21 A. I think we saw something very
22 similar or this document earlier today.
23 Q. Yes. We saw a very similar
24 document earlier today. If you'll turn with
25 me to the last page of this document where

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1 Cathy Stewart e-mails Karen Harper with a CC
2 to you on November 16th, 2009, she writes,
3 referencing the manual process, that it's a
4 process that lends itself to errors and
5 omissions.
6 Are you aware of any shipments
7 that were sent to entities on the manual do
8 not ship list before it was transitioned to
9 SDIG -- or CDIG, excuse me?
10 MR. BERG: Object to form.
11 A. I'm not aware of any.
12 QUESTIONS BY MS. KEECH:
13 Q. Okay. So when she said it's a
14 process that lends itself to errors and
15 omissions, were you aware of any of those
16 errors or omissions that had occurred?
17 A. No.
18 Q. Okay. You can set that aside.
19 (Mallinckrodt-Saffold
20 Exhibit 20 was marked for
21 identification.)
22 QUESTIONS BY MS. KEECH:
23 Q. I'm handing you what's been
24 marked as Exhibit 20, bearing Bates
25 MNK-T1_0000278389.

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1 Are you familiar with this
 2 document?
 3 A. No.
 4 Q. Any reason to doubt its
 5 authenticity?
 6 A. No.
 7 Q. Okay. So at the bottom of this
 8 e-mail thread, Karen Harper sends an e-mail
 9 to Cathy Stewart and Jim Rausch with a copy
 10 to you on November 6th, 2009, regarding the
 11 Suspicious Order Monitoring program, work
 12 instruction update, customer checklist
 13 revisions and frequently asked question edit
 14 changes.
 15 Jim then responds saying: We
 16 removed the question "Does your company
 17 verify that your customers have a Suspicious
 18 Order Monitoring program as prescribed by
 19 21 C.F.R. 1301.74" from the manufacturer's
 20 questionnaire. Should it be removed from the
 21 distributor and wholesaler questionnaires
 22 also?
 23 Are you familiar with the
 24 questionnaires that they're referencing?
 25 A. I'm familiar that we had a

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1 questionnaire.
 2 Q. And what was the purpose of the
 3 questionnaire, do you know?
 4 A. Compliance, right.
 5 Q. So Mallinckrodt would send
 6 questionnaires to its distributors and
 7 wholesalers, correct?
 8 A. Yes.
 9 Q. Okay. Did the questionnaires
 10 assist in learning more about Mallinckrodt's
 11 customers and whether they were aware of DEA
 12 requirements?
 13 A. I'm not really the author of
 14 the questionnaire nor the driver of that
 15 initiative, so I'm not comfortable commenting
 16 on the questionnaire's purpose.
 17 Q. Okay. Do you recall receiving
 18 the e-mail reflecting updates to the SOM
 19 procedures?
 20 MR. BERG: Object to form.
 21 A. No, I don't recall this. And
 22 then, you know, I would point out that aside
 23 from Karen's initial e-mail, I wasn't copied
 24 on the subsequent e-mails so it's kind of
 25 tough for me to even, you know, comment.

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1 QUESTIONS BY MS. KEECH:
 2 Q. Okay. Well, were you aware
 3 that this question was removed from the
 4 questionnaires?
 5 A. I can't recall.
 6 Q. Do you know why Mallinckrodt
 7 would have removed that question?
 8 A. I don't know. Aside from
 9 compliance, right, I don't know much about
 10 the questionnaire.
 11 Q. Okay.
 12 (Mallinckrodt-Saffold
 13 Exhibit 21 was marked for
 14 identification.)
 15 QUESTIONS BY MS. KEECH:
 16 Q. I'm handing you what's been
 17 marked as Exhibit 21, bearing Bates number
 18 MNK-T1_0004154291. This is an e-mail sent
 19 from Cathy Stewart on November 6, 2009, to
 20 you, Karen Harper and Jim Rausch.
 21 Karen then writes that she's
 22 updated the bulk checklist to remove the
 23 question relative to whether or not our
 24 customer is verifying their customer has an
 25 SOM program.

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1 MR. BERG: You know, Counsel, I
 2 know you spent a lot of time with
 3 these documents, but when you
 4 introduce them, can you just point us
 5 to where you're looking?
 6 MS. KEECH: Sure.
 7 MR. BERG: Because we haven't
 8 had a chance to review them.
 9 MS. KEECH: Sure.
 10 MR. BERG: Thanks.
 11 MS. KEECH: I'm also displaying
 12 them here on the Elmo. I don't know
 13 if you can see it.
 14 MR. BERG: I can't see it.
 15 Okay, I guess I can see some of it.
 16 But just take your time, just
 17 familiarize yourself with anything you
 18 need to.
 19 THE WITNESS: Okay, absolutely.
 20 QUESTIONS BY MS. KEECH:
 21 Q. So you were notified of this
 22 decision to remove the question from the
 23 questionnaire. Is that correct?
 24 MR. BERG: Object to form.
 25 A. Yes.

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1 QUESTIONS BY MS. KEECH:
2 Q. Was this then or is it now
3 concerning to you that this question was
4 removed?
5 A. No. I don't know enough about
6 this to really be able to register a concern
7 about a question being removed. What makes
8 me have confidence is that we're very --
9 we're working with our compliance person, so
10 I'm -- I wouldn't be concerned at all. "Bulk
11 checklist" would refer to API, so...
12 Q. Did you believe that
13 Mallinckrodt had an obligation to know its
14 customers' customers?
15 MR. BERG: Object to form.
16 A. No, that's not really my area.
17 QUESTIONS BY MS. KEECH:
18 Q. Did anyone ever discuss whether
19 Mallinckrodt had an obligation to know its
20 customer's customer with you?
21 A. I think you may be asking me
22 about privileged information. Can I have
23 a -- so --
24 MR. BERG: Well, before you
25 answer, like if you're concerned about

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1 it, let's just step outside in the
2 hall and talk about it.
3 THE WITNESS: Yes, let's.
4 MR. BERG: Is that okay?
5 MS. KEECH: Sure. Do you want
6 to --
7 MR. GOTTO: You want to take a
8 lunch break now?
9 MR. BERG: Okay. Sure.
10 MS. KEECH: Yeah.
11 THE VIDEOGRAPHER: All right.
12 Off the record at 12:18.
13 (Recess taken, 12:18?p.m. to
14 1:07?p.m.)
15 THE VIDEOGRAPHER: All right,
16 stand by. The time is 1:07, back on
17 the record.
18 QUESTIONS BY MS. KEECH:
19 Q. Thank you.
20 So before we broke earlier, I
21 asked you a question and you were going to
22 consult with your attorney, so I will
23 rephrase the question and you can answer it
24 again.
25 So apart from any conversations

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1 you may have had with counsel, did anyone
2 ever discuss with you whether Mallinckrodt
3 had an obligation to know its customer's
4 customer?
5 A. I don't recall any instances of
6 that, like a discussion on that, outside of
7 conversations with counsel.
8 Q. Okay. I'll rephrase the
9 question a little differently. So again,
10 outside of any conversation with counsel, did
11 you ever read any materials while you were at
12 Mallinckrodt or hear of this concept in any
13 form?
14 A. I don't recall.
15 Q. Okay. Thank you.
16 (Mallinckrodt-Saffold
17 Exhibit 22 was marked for
18 identification.)
19 QUESTIONS BY MS. KEECH:
20 Q. I'm handing you what has been
21 marked Exhibit 22, bearing Bates number
22 MNK-T1_0000455782.
23 Do you recognize this document?
24 A. Yes. It's similar to a
25 document you showed me earlier.

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1 Q. Okay. And what is it?
2 A. It's a meeting request.
3 Q. Is it from Karen Harper, dated
4 July 22nd, 2010?
5 A. Yes.
6 Q. And are you on the recipient
7 list?
8 A. Yes.
9 Q. Okay. And does it state a
10 meeting purpose?
11 A. It does.
12 Q. And can you please read that
13 meeting purpose?
14 A. "Recent DEA enforcement action
15 taken within industry (including two
16 Mallinckrodt customers) merits a review of
17 our existing Controlled Substance Suspicious
18 Order Monitoring Program."
19 Q. So this indicates that two of
20 Mallinckrodt's customers got into trouble
21 with the DEA. Is that correct?
22 MR. BERG: Object to form.
23 A. It certainly -- I don't know.
24 Enforcement action, right, so I don't know if
25 that's in trouble or...

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1 QUESTIONS BY MS. KEECH:
 2 Q. Sure.
 3 Does this represent that the
 4 DEA took enforcement action against two of
 5 Mallinckrodt's customers?
 6 A. It does.
 7 Q. Okay. And would you agree that
 8 because two of Mallinckrodt's customers had
 9 enforcement action taken against them that it
 10 was indicative that Mallinckrodt's Suspicious
 11 Order Monitoring program needed to be
 12 reviewed?
 13 MR. BERG: Objection to form.
 14 A. So I don't really have an
 15 opinion on that. I would defer to our
 16 compliance team.
 17 QUESTIONS BY MS. KEECH:
 18 Q. Okay. And earlier we discussed
 19 how Mallinckrodt chose to remove the question
 20 of whether its customers were verifying its
 21 customers had SOM programs in the
 22 questionnaire that it submitted.
 23 MR. BERG: Objection, form.
 24 A. So at the risk of being
 25 argumentative, I think that referred to a

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1 bulk checklist and not necessarily a
 2 questionnaire that would be, you know, used
 3 for other types of customers.
 4 QUESTIONS BY MS. KEECH:
 5 Q. But you agree that that
 6 question was removed from the bulk checklist?
 7 MR. BERG: Object to form.
 8 A. It appears so. I'm not
 9 disputing that.
 10 QUESTIONS BY MS. KEECH:
 11 Q. Okay. And do you think that
 12 knowing the answer to that question would
 13 have been helpful in assessing whether
 14 Mallinckrodt should continue shipping product
 15 to its customers?
 16 A. I don't know.
 17 MR. BERG: Object to form.
 18 QUESTIONS BY MS. KEECH:
 19 Q. Okay. So I want to go back and
 20 talk with you about your supervision of your
 21 direct reports. You indicated earlier that
 22 you supervised both Jim Rausch and Cathy
 23 Stewart. Is that correct?
 24 A. Yes.
 25 Q. Okay. Can you describe for me,

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1 aside from the monthly reports that they
 2 generated, what the nature of your
 3 supervision was? In other words, how often
 4 did you meet with them, did you have
 5 one-on-ones, how frequently did you
 6 communicate?
 7 MR. BERG: Object to form.
 8 A. Sure. It's -- I believe, you
 9 know, that we met, you know, I usually
 10 schedule weekly one-on-ones with my direct
 11 reports, so I think that would be consist- --
 12 you know, I think that's what I had done.
 13 I don't specifically remember
 14 scheduling one-on-ones with them, but it's
 15 just that's what I do, and so -- and then
 16 also -- so that's, you know, aside from the
 17 monthly reports, that's, you know, how I got
 18 updates from them.
 19 QUESTIONS BY MS. KEECH:
 20 Q. And were the weekly meetings in
 21 person?
 22 A. Yes.
 23 Q. Do you recall about how long
 24 they lasted?
 25 A. I don't specifically recall any

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1 of the details of these meetings, so it would
 2 be tough to say.
 3 Q. Okay. Do you remember if it
 4 was a standing meeting or was it just more of
 5 an infrequent pop in, check in, see if you
 6 have any updates kind of a thing?
 7 A. I really don't recall the
 8 meetings, so it's kind of tough to say. I
 9 tend to schedule standing meetings with my
 10 direct reports.
 11 Q. Do you ever recall discussing
 12 with Jim Rausch the volume of peculiar orders
 13 that he was receiving?
 14 A. No.
 15 Q. Do you ever remember him saying
 16 that he was expending a large portion of his
 17 day reviewing peculiar orders?
 18 A. No.
 19 Q. Okay. And it's your
 20 understanding that there were changes to the
 21 Suspicious Order Monitoring program over
 22 time. Is that correct?
 23 A. Yes.
 24 Q. Okay. And do you recall if any
 25 of those changes were based on the algorithm

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1 used to flag whether an order was peculiar?
2 A. I don't know a lot of the
3 details on the changes, so I'm not sure I can
4 answer that question.
5 Q. Okay. Did you know whether one
6 of the factors evaluated was the historical
7 ordering patterns of a customer?
8 A. Yes. But just kind of at that
9 level, yes, historical order patterns are
10 something that is evaluated.
11 Q. And do you recall or know
12 whether the historical averages, as part of
13 the Suspicious Order Monitoring formula, ever
14 changed?
15 MR. BERG: Object to form.
16 A. I don't recall it necessarily
17 even being averages, so I don't really recall
18 what changes would have been made to it.
19 QUESTIONS BY MS. KEECH:
20 Q. Okay. Is the term "historical
21 average threshold" familiar to you?
22 A. I don't recall hearing it.
23 Q. Okay. I'm handing you what has
24 been marked as Exhibit 23.
25 (Mallinckrodt-Saffold

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1 Exhibit 23 was marked for
2 identification.)
3 QUESTIONS BY MS. KEECH:
4 Q. Bearing Bates number
5 MNK-T1_0005708609.
6 Do you recognize this document?
7 A. No.
8 Q. It's an e-mail from Debbie
9 Digby dated May 30th, 2012, addressed to you,
10 subject: Distributor EDI 852 - fill rate
11 information for McKesson.
12 A. Yes.
13 Q. Do you have any reason to doubt
14 the authenticity of this e-mail?
15 A. No.
16 Q. And do you recall who Debbie
17 Diggy -- Digby, excuse me, is or what her
18 role at Mallinckrodt was?
19 A. No. No, sorry.
20 Q. Okay. And it indicates here
21 that you made a request for data.
22 A. Yes.
23 Q. Okay. And it appears that
24 Debbie provided EDI 852 data.
25 A. Yes.

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1 Q. What is 852 data?
2 A. So as I remember, EDI 852 data
3 is the information from like a wholesaler or
4 a distributor. 852 refers to an EDI
5 transaction. This transaction shows their
6 inventory and kind of their net -- and it can
7 show everything. It's always an inventory
8 transaction.
9 Q. Okay.
10 A. And then depending on what
11 other fields the distributor would send, it
12 may show other things as well.
13 Q. Okay. And what's the
14 significance of 852 data, if any?
15 A. So what that can show is if a
16 distributor, such as McKesson in this case,
17 says, hey, you're doing a bad job because
18 your orders aren't shipping out on time and
19 sometimes you don't have product. We say,
20 well, give us your 852 information, and we
21 can say, look, you're not having -- you know,
22 you have inventory on hand, so, yeah, we're
23 not filling your orders, but look, you're
24 still able to service your customers.
25 Q. Is 852 data something that you

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1 regularly reviewed?
2 A. No.
3 Q. Do you recall why you wanted to
4 review it in this instance?
5 A. No. I think the speculation is
6 kind of in the answer I gave of probably
7 wanting to say we're maybe not as bad as
8 you're saying we are, but I don't know for
9 sure.
10 Q. Okay. And are you familiar
11 with 867 data?
12 A. No. Like I cannot tell you
13 what it is.
14 Q. Okay. Do you know whether
15 Mallinckrodt reviewed 867 data?
16 A. I don't know what 867 data is.
17 Q. Okay. How about 844 data?
18 A. I don't know. I don't remember
19 what that is either.
20 Q. Do you recall any other data
21 sources that you reviewed in your job?
22 MR. BERG: Object to form.
23 A. Are you talking about EDI data?
24 QUESTIONS BY MS. KEECH:
25 Q. Yeah.

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1 A. Well, an 850, which is a
 2 purchase order. I didn't really review the
 3 data, but I remember, you know, because we'd
 4 process orders, so that was a good one to
 5 get. And then that's -- and then 856, which
 6 is kind of an -- I think it's an order
 7 acknowledgment, those were sometimes
 8 distributors would want to make sure we were
 9 sending them 856s. I think that's what an
 10 856 is, but I'm not...
 11 Q. Okay. Thank you.
 12 Are you familiar with the term
 13 "chargebacks"?
 14 A. Yes.
 15 Q. And what do you understand
 16 chargebacks to be?
 17 A. It's pretty limited. So I
 18 understand a chargeback refers to a
 19 transaction generated from the distributor to
 20 us or to, you know, the seller.
 21 Q. And is it your understanding
 22 that the chargeback is the difference between
 23 the list price and the contract price that
 24 reconciles the two prices to make the
 25 distributor whole?

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1 A. Yes.
 2 Q. Okay. And in your capacity as
 3 director of customer service, did you review
 4 chargeback data?
 5 A. No.
 6 Q. Did you have access to it?
 7 A. No.
 8 Q. Did you understand how the
 9 company utilized it?
 10 A. No.
 11 Q. Okay.
 12 (Mallinckrodt-Saffold
 13 Exhibit 24 was marked for
 14 identification.)
 15 QUESTIONS BY MS. KEECH:
 16 Q. I'm handing you what's been
 17 marked as Exhibit 24, bearing Bates number
 18 MNK-T1_0000299450.
 19 (Document review by witness.)
 20 QUESTIONS BY MS. KEECH:
 21 Q. Okay. Do you recognize this
 22 exhibit?
 23 A. Not really.
 24 Q. It's an e-mail from Lisa
 25 Cardetti to you and Jim Rausch dated

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1 October 27, 2011. Do you have any reason to
 2 doubt its authenticity or that it was sent to
 3 you?
 4 A. No.
 5 Q. Okay. And are you familiar
 6 with the concept of future-dating?
 7 A. Yes.
 8 Q. What is future-dating?
 9 A. So future-dating is changing
 10 the requested date on an order to a date in
 11 the future. So, you know, an order has
 12 several fields, date fields. So this is a
 13 field where if you say, hey, I don't think
 14 I'm going to be able to get you some product,
 15 and so I can cancel the order or, you know,
 16 if you want to wait a while for it, you know,
 17 I can move this out 30, 45, 50 days, and then
 18 you could change the future date, so you
 19 still knew, hey, we are expected to fill this
 20 order on this date now.
 21 Q. So when an order was
 22 future-dated, when was the product actually
 23 shipped?
 24 A. It would depend on -- you know,
 25 typically it would be on the date that we

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1 changed the future date to, if that makes
 2 sense.
 3 Q. If you received product before
 4 the date in which the order was future-dated,
 5 would it ship before that future date?
 6 A. I don't believe so.
 7 Q. Okay. And this e-mail
 8 discusses a significant increase in oxycodone
 9 15- and 30-milligram backorders. It appears
 10 that manufacturing requested that the orders
 11 be future-dated so that customers who already
 12 received their allotted monthly quality --
 13 quantity.
 14 You indicated on the first page
 15 of the document, middle of the page, in the
 16 e-mail from George Saffold to Lisa Cardetti,
 17 October 27, 2011, that you would change the
 18 notes on the order to state "Future dated Due
 19 Excess Demand per Marketing. Customer has
 20 already received their monthly allocation for
 21 October 2011."
 22 When you wrote this note, where
 23 was it actually recorded?
 24 MR. BERG: Object to form.
 25 A. So I didn't write this note on

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1 anything.
2 QUESTIONS BY MS. KEECH:
3 Q. Okay.
4 A. My team members who go in and
5 would change the dates, they would write that
6 note on the order header detail page in the
7 system of the order management system.
8 Q. So fair to say it was an
9 internal record?
10 A. Yes.
11 Q. Was this ever actually written
12 on a 222 form?
13 A. Not to my knowledge.
14 Q. So you provided the rationale
15 to your team members for what to write in
16 this instance. Is that correct?
17 MR. BERG: Object to form.
18 A. It provided the verbiage that
19 they were required to put on the order if
20 they were changing an order per this, you
21 know, kind of initiative.
22 QUESTIONS BY MS. KEECH:
23 Q. Okay. And the reason stated
24 was increased demand.
25 A. No.

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1 Q. Or excess demand. Is that
2 correct?
3 A. Excess demand, yes.
4 Q. Excess demand.
5 Are you aware of whether anyone
6 looked into the reason for the demand?
7 A. No.
8 Q. So do you know whether anyone
9 ever looked into whether the demand exceeded
10 the supply because the orders were
11 suspicious?
12 A. I wouldn't be aware of that.
13 Q. Okay. And on the third page of
14 this document, it indicates Lisa Cardetti
15 sent an e-mail on October 26, 2011, to Robert
16 Laznak.
17 Do you know who Robert Laznak
18 was?
19 A. I'm -- oh. No.
20 Q. In this e-mail to Robert or
21 Bob, Lisa indicates that the following
22 customers would have orders that would be
23 future-dated to November 1st for their
24 monthly allocation.
25 Do you see that?

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1 A. Yes.
2 Q. And it lists AmerisourceBergen?
3 A. Yes.
4 Q. And also lists Cardinal Health?
5 A. Yes.
6 Q. Okay. Do you recall the
7 presentation we discussed earlier,
8 Exhibit 10?
9 A. Do you mind if I look?
10 Q. Sure. Yeah.
11 A. Yes.
12 Q. And this e-mail thread that's
13 in front of you is dated October 2011,
14 correct?
15 A. Yes, it is.
16 Q. Okay. And Exhibit 10 is dated
17 March of 2011.
18 A. Yes.
19 Q. And in Exhibit 10, page 9 of
20 Exhibit 10 lists distributors who the DEA had
21 taken enforcement action against, correct?
22 A. Yes.
23 Q. And it discusses license
24 suspension of AmerisourceBergen and Cardinal,
25 correct?

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1 A. Yes.
2 Q. Okay. So at the time that
3 Mallinckrodt future-dated the orders for
4 these entities, Mallinckrodt was aware of
5 their prior DEA enforcement actions.
6 MR. BERG: Object to form.
7 A. Apparently, yes.
8 QUESTIONS BY MS. KEECH:
9 Q. Was that then or is that now
10 concerning to you?
11 MR. BERG: Object to form.
12 A. No.
13 (Mallinckrodt-Saffold
14 Exhibit 25 was marked for
15 identification.)
16 QUESTIONS BY MS. KEECH:
17 Q. I'm handing you what's been
18 marked as Exhibit 25, bearing Bates number
19 MNK-T1_0005711355. This is an e-mail from
20 Carla Johnson dated October 26, 2011, to you
21 with a CC to Michael Santowski regarding
22 oxycodone orders.
23 Do you recognize this document?
24 A. No.
25 Q. Any reason to doubt its

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1 authenticity?
2 A. No.
3 Q. Okay. So about in the middle
4 of the document, you sent an e-mail to Carla
5 Johnson, and who is Carla Johnson?
6 A. At the time, she was director
7 of planning.
8 Q. And in this, you -- actually,
9 can you read what you wrote to Carla?
10 A. "Hi, Carla. I just want to
11 make sure you are aware of this because I'm
12 not sure the direction on dating from Lisa is
13 consistent with our order management
14 policies. Did they run" -- do you want me to
15 read that?
16 Q. Yep.
17 A. "Did they run any of this by
18 you, because it seems like the changes you
19 made to the backorder report should address
20 manufacturing's concerns about the orders
21 showing up on backorder."
22 Q. And who is Michael Santowski?
23 A. The VP of supply chain.
24 Q. And Carla stated: Oxycodone
25 30s are the exception to the new backorder

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1 report logic because we are not storing that
2 inventory in a shippable branch plant.
3 A. Yes.
4 Q. Do you know why oxy 30s would
5 be an exception?
6 MR. BERG: Object to form.
7 A. No, other than that they are
8 not storing the inventory -- I mean, other
9 than what's stated there, no.
10 QUESTIONS BY MS. KEECH:
11 Q. Okay. And then can you read
12 what Carla wrote next, beginning with "This
13 is"?
14 A. "This is going to be an ongoing
15 issue; so I think it makes sense to take a
16 different approach. So I would say I'm in
17 alignment."
18 Q. So fair to say Carla approved
19 the proposed future-dating practice?
20 MR. BERG: Object to form.
21 A. I think that's fair.
22 QUESTIONS BY MS. KEECH:
23 Q. So when you said you weren't
24 sure that the direction on dating from Lisa
25 was consistent with management policies, do

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1 you recall which management policy or
2 policies you were referring to?
3 A. I do.
4 Q. Okay.
5 A. So all of us in supply chain,
6 you know, we're -- a big metric for us is
7 service level, how many orders we can fill,
8 and that's not -- it's usually based on
9 demand. So if we're changing the requested
10 delivery date, it -- but if they had really
11 wanted it earlier, it might kind of look like
12 we were changing the numbers to get like a
13 better fill rate. So I wanted to make sure
14 that everyone was comfortable with doing that
15 and we were making sure that we -- you know,
16 that everyone was aware of it.
17 Q. So other than sending this
18 e-mail to Carla Johnson, do you recall
19 whether you raised this issue with anyone
20 else?
21 A. Yes.
22 Q. And did you?
23 A. Yes. I raised this issue to
24 Mike Santowski, and again, for the reason of,
25 like, hey, umm, I'm changing an order or my

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1 people are changing a requested date. You
2 know, do you think this is okay in this
3 situation?
4 Q. And what response, if any, did
5 you get?
6 A. A good response. He said --
7 you know, he said yes, and then he confirmed
8 that, you know, for us to change the order,
9 there had to be a conversation with a
10 customer led by, you know, the commercial
11 organization saying, you know, hey, are you
12 okay with us changing the date, here's why
13 we're changing the date. So it wasn't just
14 like we were wholesale looking at orders that
15 were backordered, that there was actually
16 some discipline applied to this.
17 Q. So when that conversation
18 occurred with the customer, was that in
19 writing, over the phone?
20 A. I'm not sure.
21 Q. Okay. Do you know who had that
22 conversation?
23 A. I don't recall.
24 Q. Okay. Did you raise it with
25 anyone else other than Mike Santowski and

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1 Carla Johnson?
 2 A. No.
 3 Q. Okay. Were you satisfied with
 4 the answer that Mike Santowski gave you?
 5 A. Yes. In terms of raising it to
 6 other people -- let me rephrase that. I
 7 don't remember whether I did or not, but I do
 8 remember being satisfied with the answer.
 9 Q. Okay. So what was the benefit
 10 to Mallinckrodt of future-dating an order?
 11 MR. BERG: Object to form.
 12 A. I'm not 100% sure.
 13 QUESTIONS BY MS. KEECH:
 14 Q. Do you have an idea as to how
 15 it benefited Mallinckrodt in any way?
 16 A. So, yeah. I think it made
 17 it -- it made our order management system,
 18 which gives requirements to manufacturing and
 19 helps us plan our activities, match more of
 20 what we were actually doing.
 21 And then also, it made our --
 22 once all the dates matched, then you can do
 23 things like make sure you're planning the
 24 right transportation, so it just made
 25 everything more accurate.

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1 Q. Okay. And to your knowledge,
 2 was the Suspicious Order Monitoring algorithm
 3 based in part on order history of customers?
 4 MR. BERG: Object to form.
 5 A. With very limited knowledge of
 6 the actual algorithm, I understand that was
 7 one of its features.
 8 QUESTIONS BY MS. KEECH:
 9 Q. Okay. So fair to say the order
 10 history in any given month was a relevant
 11 factor in analysis of whether a customer had
 12 suspicious orders?
 13 MR. BERG: Object to form.
 14 A. Can you repeat that? I don't
 15 know if I understood the question.
 16 QUESTIONS BY MS. KEECH:
 17 Q. Sure.
 18 Did a customer's order history
 19 in any given month, was that relevant in the
 20 analysis of whether a customer had a
 21 suspicious order?
 22 A. Again, without knowing the --
 23 you know, the algorithm rules, it would be
 24 hard to say.
 25 Q. So just generally speaking,

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1 you're not sure whether a customer's ordering
 2 history was significant when evaluating its
 3 orders?
 4 MR. BERG: Object to form.
 5 A. So I believe it was, you know,
 6 but I don't know specifically what elements
 7 of order history were, you know, used.
 8 QUESTIONS BY MS. KEECH:
 9 Q. Okay. So it's fair to say that
 10 future-dating allowed Mallinckrodt to sell
 11 opioids to a wholesale distributor customer
 12 without triggering some kind of suspicious
 13 order review?
 14 MR. BERG: Object to form.
 15 A. I would say that is not fair to
 16 say.
 17 QUESTIONS BY MS. KEECH:
 18 Q. So do you know whether, when
 19 orders were future-dated, an evaluation
 20 occurred of that distributor for whether its
 21 orders were suspicious --
 22 MR. BERG: Object --
 23 QUESTIONS BY MS. KEECH:
 24 Q. -- prior to the future-dating?
 25 MR. BERG: Object to form.

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1 A. My understanding of the
 2 Suspicious Order Management program and how
 3 it interacted with the order management
 4 system was that every order was reviewed.
 5 QUESTIONS BY MS. KEECH:
 6 Q. Okay. If an order was
 7 future-dated, the sales to that particular
 8 wholesale distributor would not exceed the
 9 threshold for review set by the Suspicious
 10 Order Monitoring algorithm for the time
 11 period in which the sale in fact occurred.
 12 Is that correct?
 13 MR. BERG: Objection. Object
 14 to form.
 15 A. I'm not sure. There were
 16 several dates on an order, one of them being
 17 order date, which is immutable, or at least I
 18 don't think you could move it, and we never
 19 did. And the other was requested date, which
 20 referred to requested delivery date.
 21 So I'm not sure how the -- what
 22 date Suspicious Order Monitoring looked at,
 23 but we made sure we maintained the integrity
 24 of the order by not altering that order date
 25 and only the requested delivery date because

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1 we had a conversation with the customer
2 saying, hey, I can't get it to you this date,
3 can you have it later. They said yes, then
4 we said, okay, we're changing your date to
5 here.
6 So I'm not sure how that
7 interacts with Suspicious Order Monitoring.
8 QUESTIONS BY MS. KEECH:
9 Q. Okay. Do you know whether 222
10 forms have an expiration date on them?
11 A. I do know they do.
12 Q. Okay.
13 (Mallinckrodt-Saffold
14 Exhibit 26 was marked for
15 identification.)
16 QUESTIONS BY MS. KEECH:
17 Q. I'm handing you what has been
18 marked Exhibit 26, bearing Bates number
19 MNK-T1_0002742739.
20 A. Thank you.
21 Q. This is an e-mail sent from Jim
22 Rausch on October 27, 2011, and you were
23 included on the CC field, subject line:
24 Oxycodone orders.
25 Do you recognize this document?

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1 A. I need a moment.
2 (Document review by witness.)
3 A. It looks very similar to the
4 prior -- an e-mail you showed me prior, maybe
5 with just some more comments on it, so yes.
6 QUESTIONS BY MS. KEECH:
7 Q. Okay. And on the first page of
8 this document, Sharron Banks sent an e-mail
9 on October 27th, 2011, to Jim Rausch and a
10 number of others with a CC to you and stated:
11 Jim, there's a possibility that the 222 forms
12 may expire by the desired requested date.
13 And then can you read Jim's
14 response at the top of the document?
15 A. Sure.
16 "We'll see how many orders we
17 have that won't allow us to future date it to
18 new date because of the 222 form expiration
19 date. If that happens we will need -- would
20 need to ask the customer to send us a new
21 form with the reason that we won't have any
22 more oxycodone for them until the future date
23 and reenter the order with the new 222 form.
24 We'll discuss it more if and when it comes
25 up."

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1 Q. Do you see anything wrong with
2 that practice?
3 MR. BERG: Object to form.
4 A. No.
5 (Mallinckrodt-Saffold
6 Exhibit 27 was marked for
7 identification.)
8 QUESTIONS BY MS. KEECH:
9 Q. Okay. I'm handing you what's
10 been marked Exhibit 27, bearing Bates number
11 MNK-T1_000299509.
12 Do you remember this document?
13 A. No.
14 Q. Okay. Any reason to doubt its
15 authenticity?
16 A. No.
17 Q. Okay. And this is an e-mail
18 sent from Lisa Cardetti to Ginger Collier
19 with a CC to both you and Jim Rausch sent
20 October 4th, 2011. The subject line: Pharma
21 Backorder Report - Summary.
22 And Lisa writes: In working
23 with customer service, we've eliminated the
24 backorders on oxycodone IR by future-dating
25 orders. I wanted to make you aware that this

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1 initiative/process will continue through
2 January.
3 So based on your recollection
4 and review of these documents, is it fair to
5 say that the future-dating process began in
6 October of 2011?
7 A. Yes.
8 Q. Are you aware of whether
9 Mallinckrodt future-dated any orders prior to
10 2011?
11 A. No.
12 Q. Okay. And this indicates that
13 it continued through January 2012?
14 A. Yes.
15 Q. And are you aware of whether
16 Mallinckrodt continued to future-date any
17 orders after January of 2012?
18 A. I don't recall.
19 Q. Okay. Is future-dating
20 authorized by the DEA?
21 MR. BERG: Object to form.
22 A. I don't know.
23 QUESTIONS BY MS. KEECH:
24 Q. Do you know who Pat Wall is?
25 A. Yes.

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1 Q. Who is Pat Wall?

2 A. Pat Wall is a customer service

3 agent. She worked as -- in respiratory

4 customer service and then respiratory

5 customer service as a supervisor and then

6 went over to dosage customer service as kind

7 of an agent.

8 (Mallinckrodt-Saffold

9 Exhibit 28 was marked for

10 identification.)

11 QUESTIONS BY MS. KEECH:

12 Q. Okay. I'm handing you a

13 document labeled Exhibit 28, bearing Bates

14 number MNK-T1_0004595958.

15 (Document review by witness.)

16 QUESTIONS BY MS. KEECH:

17 Q. Do you recognize this document?

18 A. Yes.

19 Q. What is it?

20 A. It is an FAQ for the purpose of

21 loading it into a knowledge management system

22 I was trying to launch.

23 Q. So did you have a role in

24 generating this document?

25 A. No.

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1 Q. Okay. But you're familiar with

2 it?

3 A. Yes.

4 Q. Okay. And can you read the

5 fifth sentence on the first page, beginning

6 with "Can 222 forms be post or future dated"?

7 A. "Can 222 forms be post or

8 future dated? No, 222 forms are dated on the

9 actual date they are completed."

10 Q. And what about the

11 second-to-last question on page 1, beginning

12 "What if I make a mistake while completing

13 the 222 form?"

14 A. "What if I make a mistake while

15 completing the 222 form? Can I correct it?

16 No, there can be no corrections or markovers

17 on a 222 form. You will need to complete and

18 send in another 222 form that is completed

19 correctly."

20 Q. So fair to say it's important

21 that the 222 forms are filled out correctly?

22 A. Yes.

23 Q. And is it okay to ship a

24 product without a 222 form?

25 A. If -- depending on the schedule

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1 of the product, so --

2 Q. So let me clarify it. Would it

3 be a violation of DEA regulations to ship a

4 Schedule II narcotic without a 222 form?

5 MR. BERG: Object to form.

6 A. I believe so, yes.

7 QUESTIONS BY MS. KEECH:

8 Q. Thank you.

9 A. Oh, and keep in mind also,

10 CSOS, right, so all Schedule II orders do not

11 require a 222 form; only those that are

12 manual, right. If a distributor or

13 wholesaler orders electronically using the

14 Controlled Substance Ordering System, that

15 kind of 222 compliance activity is handled

16 electronically. Then an order would not have

17 that.

18 Q. Thanks for clarifying.

19 A. Sorry.

20 Q. That's okay.

21 THE WITNESS: Is this a good

22 time to break, maybe, and see if the

23 coffee is here?

24 MS. KEECH: Yes, we can do

25 that. That's a good idea.

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1 THE VIDEOGRAPHER: Off the

2 record at 1:52.

3 (Recess taken, 1:52?p.m. to

4 2:00?p.m.)

5 THE VIDEOGRAPHER: All right,

6 stand by. The time is 2:00 o'clock

7 p.m. Back on the record, beginning of

8 File 3.

9 (Mallinckrodt-Saffold

10 Exhibit 29 was marked for

11 identification.)

12 QUESTIONS BY MS. KEECH:

13 Q. Okay. I'm handing you what's

14 been marked as Exhibit 29, bearing Bates

15 number MNK-T1_0000368976.

16 Do you recognize this document?

17 A. No.

18 Q. Any reason to doubt its

19 authenticity?

20 A. No.

21 Q. And this is a 2010 e-mail chain

22 started by Cheryl Nelson regarding the state

23 of Florida and oxycodone prices.

24 Can you read aloud at the

25 bottom of the first page?

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1 A. "We have received numerous
2 calls this week from persons living in
3 Florida who are trying to have their oxy
4 30-milligram prescriptions filled. They are
5 complaining that the pharmacies are
6 price-gouging by charging 5 and 6 dollars per
7 pill versus 1.50 the last time they had their
8 prescriptions filled, if the pharmacy has the
9 product at all. When a person will give me
10 their name and phone number, I take it, but
11 some just won't give that information."
12 Q. And you were CC'd on that
13 e-mail?
14 A. Yes.
15 Q. Okay.
16 A. Yes.
17 Q. Okay. So fair to say that you
18 were notified about customer service
19 complaints indicating that pharmacies in
20 Florida were increasing their oxy prices and
21 price-gouging by 5 to 6 dollars a pill?
22 A. Yes.
23 Q. Okay. And you responded to
24 this e-mail to Mike Gunning and Ginger
25 Collier. And who is Mike Gunning?

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1 A. I don't know his title. He's
2 kind of like the head guy in the controlled
3 substance -- or in the dosage group.
4 Q. Okay. And can you please read
5 what you wrote to Mike and Ginger?
6 A. "Just a note to let you know
7 that not only is the frequency of calls
8 regarding oxy availability in Florida picking
9 up but also the nature of the complaints are
10 changing from simple availability to
11 price-gouging and availability. We are
12 sticking with our message that we have not
13 interrupted our supply to wholesalers and
14 that these issues are the result of scrutiny
15 by the DEA in the state of Florida."
16 Q. And how did you become aware of
17 the frequency of the call increases?
18 A. I really don't remember.
19 Q. Do you know when you would have
20 become aware of that?
21 A. I really don't remember.
22 Q. Okay. Was it at all concerning
23 to you when you learned of this situation in
24 Florida?
25 A. I don't really remember the

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1 situation.
2 Q. Okay. When you said "We are
3 sticking with our messaging," do you recall
4 who determined the content of this message?
5 A. I really don't remember this,
6 this instance.
7 Q. Okay. Ginger writes at the top
8 of the e-mail, "I am assuming these are cash
9 customers."
10 What's the significance, if
11 anything, of customers paying in cash?
12 MR. BERG: Object to form.
13 A. I don't know.
14 QUESTIONS BY MS. KEECH:
15 Q. Have you ever heard anyone
16 indicate that paying in cash for opioids is a
17 possible indicator of diversion?
18 A. No.
19 Q. Do you know whether
20 Mallinckrodt determines whether the customers
21 were independent or retail pharmacies?
22 MR. BERG: Object to form.
23 A. I'm sorry, what was the
24 question?
25 QUESTIONS BY MS. KEECH:

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1 Q. Do you know whether
2 Mallinckrodt determined whether the customers
3 were independent or retail pharmacies?
4 MR. BERG: Object to form.
5 A. I don't know.
6 QUESTIONS BY MS. KEECH:
7 Q. Okay.
8 (Mallinckrodt-Saffold
9 Exhibit 30 was marked for
10 identification.)
11 QUESTIONS BY MS. KEECH:
12 Q. I'm handing you what's been
13 marked as Exhibit 30, bearing Bates number
14 MNK-T1_0000299364.
15 A. Thank you.
16 (Document review by witness.)
17 QUESTIONS BY MS. KEECH:
18 Q. Do you recognize this document?
19 A. No.
20 Q. Any reason to doubt its
21 authenticity?
22 A. No.
23 Q. Okay. This appears to be a
24 document sent from Cheryl Nelson to you and
25 Jim Rausch with a CC to Brenda Rehkop in

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1 September of 2011.
2 A. Yes.
3 Q. And Jim e-mailed you, if you
4 turn to page 2, checking to see if orders
5 should still be cancelled. Is that correct?
6 A. Yes.
7 Q. Cheryl then says -- whoops --
8 "I have cancelled this line and did not
9 reenter it as it is my understanding that we
10 are not shipping 15- or 30-milligram oxy to
11 Florida."
12 Do you know why there was a
13 decision or concern not to ship oxy 15 or 30s
14 to Florida?
15 A. I don't remember.
16 Q. Are you aware of whether oxy
17 15s and 30s were pills that were commonly
18 abused?
19 A. Yes. I am aware, and I believe
20 they were.
21 Q. Are you aware of what
22 precipitated the discussion or decision not
23 to ship oxy 15s and 30s to Florida?
24 A. No.
25 Q. And do you know what decision

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1 Mallinckrodt ultimately made with regard to
2 shipping oxy 15s and 30s to Florida?
3 A. I really don't remember this,
4 so no.
5 Q. Okay. So you don't remember
6 writing, "While it's my expectation that we
7 may not be shipping the 15s and 30s to
8 Florida, I'm not sure how well that decision
9 has been finalized and communicated"?
10 MR. BERG: Object to form.
11 A. Yeah. I don't remember this.
12 (Mallinckrodt-Saffold
13 Exhibit 31 was marked for
14 identification.)
15 QUESTIONS BY MS. KEECH:
16 Q. I'm handing you Exhibit 31,
17 bearing Bates number MNK-T1_0003064400.
18 (Document review by witness.)
19 QUESTIONS BY MS. KEECH:
20 Q. So I've handed you an internal
21 e-mail chain regarding a series of orders for
22 oxycodone which were accidentally shipped.
23 Do you recall this incident?
24 A. No.
25 Q. Do you recognize this document?

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1 A. No.
2 Q. Any reason to doubt its
3 authenticity?
4 A. No.
5 Q. Okay. So in this document, you
6 sent an e-mail to Michael Santowski regarding
7 these orders that were accidentally shipped.
8 The first page, third paragraph, can you read
9 the sentence beginning with the word
10 "Apparently"?
11 A. "Apparently the product was
12 pulled back from the orders and set to the
13 side. It appears, however, the next shift
14 came in and assumed they were left off these
15 orders unintentionally and then shipped them
16 out."
17 Q. And then you provided a
18 timeline for each of the orders?
19 A. Yes.
20 Q. And this shows that 84 bottles
21 went to ABC in Orlando, Florida?
22 A. Yes.
23 Q. It also shows that 48 bottles
24 of 30-milligram oxy went to Prescription
25 Supply in Northwood, Ohio?

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1 A. Yes.
2 Q. And it also shows that an
3 undisclosed amount was shipped to ABC in
4 Sacramento, California?
5 A. Yes.
6 Q. So accidentally shipping orders
7 is not an ideal scenario from a customer
8 service aspect, correct?
9 A. Correct.
10 Q. It's actually pretty bad,
11 right?
12 MR. BERG: Object to form.
13 A. Yeah. Yes.
14 QUESTIONS BY MS. KEECH:
15 Q. And you e-mailed Michael
16 Santowski alerting him to this situation,
17 correct?
18 A. Yes.
19 Q. And who is Michael Santowski?
20 A. He's my direct supervisor.
21 Q. Okay. How frequently do you
22 recall communicating with him?
23 A. Pretty frequently. He was my
24 direct supervisor.
25 Q. Okay. Would you agree that

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1 shipping orders that were not supposed to be
2 shipped is an example of diversion?
3 MR. BERG: Object to form.
4 A. I don't know if it is.
5 QUESTIONS BY MS. KEECH:
6 Q. Is it an example of lack of
7 internal controls?
8 MR. BERG: Object to form.
9 A. No, it's not.
10 QUESTIONS BY MS. KEECH:
11 Q. Is this example an example of
12 lack of communication?
13 A. No.
14 Q. Do you know whether this event
15 was reported to the DEA?
16 A. I do not know.
17 Q. Do you know what, if anything,
18 happened after you sent this e-mail?
19 A. I don't remember.
20 Q. Okay.
21 (Mallinckrodt-Saffold
22 Exhibit 32 was marked for
23 identification.)
24 QUESTIONS BY MS. KEECH:
25 Q. I'm handing you what's been

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1 marked as Exhibit 32, bearing Bates stamp
2 MNK-T1_0000279164.
3 (Document review by witness.)
4 QUESTIONS BY MS. KEECH:
5 Q. Okay? Do you recall receiving
6 this e-mail?
7 A. No.
8 Q. Any reason to doubt its
9 authenticity?
10 A. Well, I didn't ever receive
11 this e-mail.
12 Q. Correct. You were referenced
13 in this e-mail. Do you recall, thank you --
14 this indicates this e-mail's sent from Karen
15 Harper to JoAnne Levy dated June 17th, 2010,
16 subject line: Conference Call with Customer
17 Service and Compliance - Harvard and Sunshine
18 DEA Registration Suspensions.
19 And Karen writes: JoAnne,
20 yesterday I set up a call for this morning
21 with me, George Saffold, Jim Rausch and
22 Eileen to discuss customer registrant DEA
23 license suspensions and Mallinckrodt
24 Suspicious Order Monitoring.
25 Do you recall ever having a

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1 conversation with those individuals regarding
2 customer registrant DEA license suspensions?
3 A. I don't recall, like, specific
4 conversations about this.
5 Q. Do you recall talking with
6 anyone about Mallinckrodt [sic] about the
7 license suspensions of either Harvard or
8 Sunrise?
9 A. I don't recall talking with
10 anybody about it. I recall that Harvard was
11 suspended.
12 Q. Okay. Maybe I'll expand that
13 question. Do you recall any communications
14 regarding the DEA license suspensions of
15 Harvard?
16 A. Not specifically, no.
17 Q. Even if you don't recall the
18 content of the communications, do you recall
19 whether there were any communications or any
20 reference at all to either the Harvard or
21 Sunrise?
22 A. Yes.
23 Q. Okay. And what do you recall?
24 A. I recall that we were notified
25 that Harvard was suspended.

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1 Q. Do you recall who notified you?
2 A. No. I -- no. I think it was
3 Karen, but I'm not 100% sure.
4 Q. Do you recall how you learned
5 about it?
6 A. No.
7 Q. Do you remember the content of
8 discussions after learning about DEA license
9 suspensions of Mallinckrodt customers?
10 A. No.
11 Q. Do you recall the action plan
12 that Mallinckrodt took after learning of DEA
13 license suspensions?
14 MR. BERG: Object to form.
15 A. I recall that we took some
16 actions and I recall some of the actions, but
17 I don't think I could tell you the whole
18 action plan.
19 QUESTIONS BY MS. KEECH:
20 Q. Okay. And in this e-mail,
21 Karen also writes, "I'm pretty confident we
22 can pull in the reins and keep the situation
23 under control," and this was dated June
24 of 2010.
25 A. Yes.

<p style="text-align: right;">Page 182</p> <p>1 Q. Are you aware of whether any of 2 Mallinckrodt's customers had any enforcement 3 action after June of 2010? 4 MR. BERG: Object to form. 5 A. I don't recall. 6 QUESTIONS BY MS. KEECH: 7 Q. Okay. 8 (Sotto voce discussion.) 9 (Mallinckrodt-Saffold 10 Exhibit 33 was marked for 11 identification.) 12 QUESTIONS BY MS. KEECH: 13 Q. Okay. I'm handing you what's 14 been marked as Exhibit 33 -- 15 A. Thank you. 16 Q. -- bearing Bates 17 MNK-T1_0000495396. 18 (Document review by witness.) 19 QUESTIONS BY MS. KEECH: 20 Q. Okay. Are you familiar with 21 this document? 22 A. No. 23 Q. Any reason to doubt its 24 authenticity? 25 A. No.</p>	<p style="text-align: right;">Page 184</p> <p>1 also indicates that Masters received the 2 fentanyl patch and morphine sulfate, which is 3 a Schedule II controlled substance, correct? 4 A. So methylphenidate is a 5 nonnarcotic C-II. Is that your question? 6 Q. Okay. But the fentanyl 7 patch -- 8 A. Is a C-II, I believe. 9 Q. Okay. Thank you. 10 Does reviewing this e-mail 11 thread refresh your recollection of what 12 happened? 13 A. Yes. 14 Q. And can you describe what 15 happened? 16 A. So I can't speak to, you know, 17 every aspect of it. But in general terms, we 18 had some product ordered and we had, you 19 know, product restricted, and some of the 20 product that should have been restricted, it 21 was ordered. We detected that, and we were 22 able to get the product back and off the 23 market, and then, you know, made sure that we 24 were communicating that, hey, this happened, 25 let's make sure we don't do this again.</p>
<p style="text-align: right;">Page 183</p> <p>1 Q. Okay. And this is an e-mail 2 thread. The top of the e-mail thread, the 3 e-mail is from you to Brenda Rehkop, Jim 4 Rausch and Karen Harper dated July 13th, 5 2011, regarding Masters recent shipments - 6 G. Saffold recommendation for systems review. 7 A. Yes. 8 Q. And towards the bottom of the 9 e-mail thread on page 2, Karen Harper sends 10 an e-mail to Jane Williams indicating that 11 George Saffold advised this morning that 12 Masters has gotten two shipments since 13 Mallinckrodt imposed shipping restrictions on 14 this account within the scope of Suspicious 15 Order Monitoring. 16 Do you recall this occurring? 17 A. A little. Like kind of 18 vaguely, yes. 19 Q. Right. Reading this 20 document -- 21 A. Yes. 22 Q. -- refreshes your recollection 23 a little bit? 24 A. Yes. 25 Q. Okay. And this e-mail thread</p>	<p style="text-align: right;">Page 185</p> <p>1 Q. Okay. And at the top of this 2 e-mail thread, you write an e-mail to Karen 3 Harper where you say: This reveals a clear 4 gap in our process. I think we should review 5 it cradle to grave to see where we can 6 improve it first to make sure that the time 7 from customer notification to restricting 8 shipments is more immediate, and second, to 9 ensure e -- 10 A. We, probably, right. 11 Q. -- cannot ship out any product 12 once we have placed these restrictions on the 13 customer. 14 A. Yes. 15 Q. So you acknowledge that there 16 was a gap in the process at that time. 17 A. Yes. 18 Q. Okay. And what, if anything, 19 do you recall that was done after you sent 20 this e-mail? 21 A. I don't recall specifically 22 what was done. I do remember there was -- 23 you know, that cradle to grave did occur. I 24 don't think I was in that actual meeting 25 where they kind of mapped it out and felt</p>

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1 like they closed the gaps.
2 Q. Okay. And in this document
3 also appears that in July of 2011,
4 Mallinckrodt was placing restrictions on five
5 accounts, in the bottom of this first page on
6 to the second page.
7 A. Yes.
8 Q. And what were those five
9 accounts?
10 A. I'm reading them from here:
11 KeySource, Masters, Harvard, Cedardale, and
12 Sunrise.
13 Q. Okay. And were you aware of
14 whether any of those entities had any DEA
15 enforcement action against them?
16 A. No, I was not aware.
17 Let me rephrase that. I don't
18 recall being aware of any, right. I just...
19 (Sotto voce discussion.)
20 (Mallinckrodt-Saffold
21 Exhibit 34 was marked for
22 identification.)
23 QUESTIONS BY MS. KEECH:
24 Q. I'm handing you what's been
25 marked as Exhibit 34, bearing

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1 MNK-T1_0004604436.
2 A. Okay.
3 Q. Do you recognize this document?
4 A. No.
5 Q. Okay. Any reason to doubt its
6 authenticity?
7 A. No.
8 Q. Okay. So this is an e-mail
9 from Karen Harper dated July 13th, 2011, to
10 Steven Becker with a CC to a number of
11 people, including you.
12 And Karen sends a list of
13 Mallinckrodt's SKUs noting products Masters
14 will not be receiving in the future given
15 current SOM program restrictions. Karen then
16 writes -- this is on the first page,
17 paragraph 3 -- can you read what she says
18 beginning with the paragraph with your name?
19 A. "George Saffold and I are
20 meeting Friday to identify improvements in
21 our internal communications system from the
22 time customer notification occurs to placing
23 restrictions on the customer account and then
24 to ensure that systems support the customer
25 account restrictions."

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1 Q. Do you recall ever having that
2 conversation with Karen?
3 A. No, I don't recall it.
4 Q. And in 2011, you were in a
5 customer service capacity. Is that correct?
6 A. Yes.
7 Q. Was anyone, to your knowledge,
8 in customer service receiving any kind of
9 compensation that was tied to sales numbers?
10 A. I don't recall.
11 Q. Is it possible?
12 A. You know, I don't recall.
13 Q. Okay. What about your personal
14 compensation scheme?
15 A. I don't recall what my scheme
16 was that year.
17 Q. Okay. But fair to say in 2011,
18 you were working with Karen Harper in some
19 capacity to assist with compliance?
20 A. Yes.
21 Q. Okay. And do you see any
22 conflict with assisting Karen with compliance
23 and determining -- strike that.
24 Do you see any conflict with
25 assisting with compliance while working in a

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1 customer service capacity?
2 A. No. It's kind of the opposite.
3 Part of service is servicing the customer in
4 a compliant manner.
5 Q. Do you know whether the issue
6 was ever raised internally at Mallinckrodt
7 about whether there was a conflict in
8 customer service being involved in Suspicious
9 Order Monitoring?
10 A. I wouldn't know.
11 Q. Do you know whether the DEA
12 ever raised this as an issue?
13 A. I wouldn't know.
14 Q. Okay.
15 (Sotto voce discussion.)
16 (Mallinckrodt-Saffold
17 Exhibit 35 was marked for
18 identification.)
19 QUESTIONS BY MS. KEECH:
20 Q. I'm handing you what's been
21 marked as Exhibit 35, bearing Bates number
22 MNK-T1_0004155087.
23 (Document review by witness.)
24 QUESTIONS BY MS. KEECH:
25 Q. All right. After reviewing

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1 that e-mail, does this refresh your
 2 recollection of anything?
 3 A. No.
 4 Q. No? Okay. Don't recognize
 5 this e-mail?
 6 A. No, I don't.
 7 Q. Do you have any reason to doubt
 8 its authenticity?
 9 A. No, I don't.
 10 Q. So this e-mail thread discusses
 11 a discrepancy in ordering. At the top of the
 12 e-mail you sent an e-mail dated January 23rd,
 13 2012, to Jim Rausch regarding a forward of an
 14 ABC order entry issue, customer requests
 15 corrective actions.
 16 So this e-mail concerns a large
 17 error in product shipment to
 18 AmerisourceBergen. AmerisourceBergen's
 19 purchase order was for 42 and the quantity
 20 ordered was 732, and I'm referring to page 3
 21 of this document about halfway down in the
 22 e-mail from Jeff Angeloni to Brenda Lindsey
 23 and others.
 24 A. I'm sorry, I'm not finding...
 25 oh, thanks. Okay. Thank you.

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1 Q. Okay. And at the top of the
 2 e-mail thread you write to Jim, "Can you
 3 respond to all on copy outlining the
 4 corrective actions in place."
 5 A. Yes.
 6 Q. Do you know what, if any,
 7 corrective actions happened?
 8 A. I really don't recall this
 9 situation.
 10 Q. Okay. If you don't recall this
 11 particular instance, do you recall whether
 12 there was a procedure in general for when
 13 more of a product shipped than what was
 14 ordered?
 15 A. A procedure? No, I don't
 16 think -- you know, I think that was highly
 17 anomalous, so I don't know if we'd have like
 18 a procedure.
 19 Q. So fair to say that this didn't
 20 happen very frequently?
 21 A. Yes.
 22 Q. Okay. And how would you define
 23 not very frequently?
 24 A. As in -- as in probably this
 25 being -- as in thinking that this situation

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1 as described is probably, you know, the only
 2 instance.
 3 Q. Okay.
 4 (Mallinckrodt-Saffold
 5 Exhibit 36 was marked for
 6 identification.)
 7 QUESTIONS BY MS. KEECH:
 8 Q. I'm handing you what's been
 9 marked as Exhibit 36.
 10 A. Thank you.
 11 Q. Bearing the Bates
 12 MNK-T1_0007823812. And this is an e-mail
 13 from Karen Harper to JoAnne Levy with a CC to
 14 you dated September 15th, 2009. Subject
 15 line: Shipment of oxycodone to DSM prior to
 16 222 form receipt.
 17 (Document review by witness.)
 18 A. Yes, I see it.
 19 QUESTIONS BY MS. KEECH:
 20 Q. Okay. Have you ever seen this
 21 document before, that you recall?
 22 A. Not that I recall.
 23 Q. Any reason to doubt its
 24 authenticity?
 25 A. No.

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1 Q. Okay. And you've had an
 2 opportunity to review this e-mail. It's an
 3 e-mail regarding shipment of oxycodone
 4 without first having a 222 form receipt. Is
 5 that correct?
 6 A. Yes.
 7 Q. And Karen writes at the top of
 8 the e-mail, paragraph two -- can you read
 9 that sentence?
 10 A. "The upside is that DEA Quota
 11 Section indicated DSM now has quota to keep
 12 the material. However, this does not absolve
 13 us of the fact that we shipped without a DEA
 14 222 form."
 15 Q. And is it permissible to ship
 16 this type of product without a 222 form?
 17 A. No.
 18 Q. Do you know when this incident
 19 was reported to the DEA?
 20 A. I don't have knowledge of it,
 21 but just even reading this e-mail, it really
 22 appears it was.
 23 Q. And fair to say that was an
 24 error on Mallinckrodt's part to ship without
 25 a 222 form in this instance?

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1 A. I don't know the specific
2 circumstances, but I think so, yes.
3 Q. Okay. You testified earlier
4 that Jim Rausch reviewed peculiar order
5 reports. Is that correct?
6 A. Yes.
7 Q. Okay. Are you aware of whether
8 customer service managers reviewed every
9 peculiar or unusual order that was identified
10 by Mallinckrodt?
11 A. Yes. My understanding is that
12 was -- for a period of time, that was
13 required.
14 Q. Okay. And was that required by
15 managers or also customer service
16 representatives?
17 MR. BERG: Object to form.
18 A. I think it was required by
19 compliance for customer service to review
20 these orders.
21 QUESTIONS BY MS. KEECH:
22 Q. And who within customer service
23 had the responsibility to review them?
24 A. So Jim had the responsibility
25 to review them.

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1 Q. Okay.
2 A. He -- which would not preclude
3 him from asking agents, hey, you know, look
4 at this -- again, who are more familiar with
5 the customers in some instances. You know,
6 tell me -- talk to me about this order, what
7 are your thoughts, who do I contact, you
8 know, with questions and those things.
9 Q. So it was the managers'
10 ultimate responsibility, but it wasn't
11 uncommon for them to defer to representatives
12 if they had questions?
13 A. Certainly it was the managers'
14 ultimate responsibility. I'm not sure if
15 they deferred or they just asked questions.
16 Q. Okay.
17 (Sotto voce discussion.)
18 QUESTIONS BY MS. KEECH:
19 Q. In the reports that Jim Rausch
20 reviewed --
21 A. Yes.
22 Q. -- internally for peculiar
23 orders, do you know whether those were
24 submitted to the DEA?
25 A. I don't know.

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1 MS. KEECH: Okay. I think
2 that's all I have for now. I'm going
3 to turn it over to Tennessee, but I
4 may have some questions later on this
5 afternoon.
6 THE WITNESS: Okay.
7 MS. KEECH: Do you want to take
8 a break before we transition?
9 MR. GASTEL: Yeah, can we just
10 take five minutes?
11 MS. KEECH: Sure, okay. Thank
12 you.
13 THE VIDEOGRAPHER: Off the
14 record, 2:46.
15 (Recess taken, 2:46?p.m. to
16 2:53?p.m.)
17 THE VIDEOGRAPHER: All right,
18 stand by. The time is 2:53. Back on
19 the record.
20 EXAMINATION
21 QUESTIONS BY MR. GASTEL:
22 Q. Good afternoon, Mr. Saffold.
23 MR. GASTEL: Before I get
24 started, I lodge a standard objection.
25 Mr. O'Connor has been letting me just

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1 say the standard objection. Is that
2 okay if I lodge my standard objection?
3 MR. BERG: It is okay.
4 QUESTIONS BY MR. GASTEL:
5 Q. Subject to that objection, I
6 represent plaintiffs who are in a Tennessee
7 lawsuit involving slightly different claims
8 than the lawsuit that Ms. Keech was asking
9 you questions about earlier. Before I get
10 started about sort of Tennessee-specific
11 stuff, I want to ask just a couple of
12 preliminary questions.
13 What is your full residential
14 address, Mr. Saffold?
15 A. 7013 Reatta Court, and that's
16 R-E-A-T-T-A, Court, North Richland Hills,
17 Texas 76182.
18 Q. And how long have you lived
19 there?
20 A. Since May of '17.
21 Q. And who lives there with you?
22 A. My wife, Sarah, and my two
23 sons, Spencer and Max.
24 Q. And do you have any plans to
25 move in the foreseeable future?

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1 A. No.
2 Q. Prior to that, were you living
3 in or near St. Louis, Missouri?
4 A. Yes.
5 Q. And that's where you were
6 living when you were working with Covidien
7 and Mallinckrodt?
8 A. Yes.
9 Q. Earlier today you had mentioned
10 that in preparation for today's deposition,
11 you had met two times with counsel.
12 Do you recall that testimony?
13 A. Yes.
14 Q. How long were those meetings?
15 A. A few hours.
16 Q. When was the first meeting?
17 A. In December, I think. Yeah.
18 Q. December of --
19 A. Oh, wait. Was it -- you know
20 what, actually, it was either in December or
21 January. I can't remember which. I'm sorry.
22 Q. That's all right.
23 And was that an in-person
24 interview or was that a conference call?
25 A. It was in person.

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1 Q. Was it here in Texas?
2 A. Yes.
3 Q. And what counsel was present?
4 A. Counsel from Ropes & Gray.
5 Q. Is it the same counsel here
6 today?
7 A. No. There's some same and some
8 different.
9 Q. And then when was the second
10 meeting?
11 A. Yesterday.
12 Q. And approximately how long was
13 that meeting?
14 A. A few hours.
15 Q. When you say "a few hours," do
16 you mean one to two hours, three to four
17 hours?
18 A. Four-ish. Four.
19 Q. And I assume that that meeting
20 was here in Texas?
21 A. Yes.
22 Q. And that was a meeting with
23 counsel who are present today?
24 A. Again, no. Some counsel.
25 Cassandra was there, present. Nick wasn't.

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1 Q. Got it.
2 And you're not currently
3 employed by Mallinckrodt, correct?
4 A. Correct.
5 Q. You're currently employed
6 where?
7 A. At VF Corporation, Dickies, in
8 Fort Worth, Texas.
9 Q. So you had to take time off of
10 work yesterday and today for this deposition,
11 correct?
12 A. Yes.
13 Q. Is Mallinckrodt paying for your
14 time today?
15 A. No.
16 Q. Did you take vacation time from
17 your current employer?
18 A. Yes.
19 Q. Do you know anything specific
20 about the Tennessee litigation?
21 A. No.
22 Q. Have you ever reviewed the
23 complaints -- any of the complaints filed in
24 the Tennessee litigation?
25 A. No.

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1 Q. In your work for Mallinckrodt
2 or Covidien, did you ever travel to the state
3 of Tennessee for your work?
4 A. I don't recall. Oh, I do
5 recall one instance. I went to Memphis to
6 meet with a 3PL, which is a third-party
7 logistics provider, who handled some medicine
8 for us, a brand that we had just purchased,
9 and just to meet with them in Memphis or kind
10 of outside Memphis. So -- I think that's the
11 only specific time I remember. There could
12 have been others.
13 Q. Was that third-party vendor
14 FedEx?
15 A. No. It was a division of
16 Cardinal, but very far down because it was
17 like in the 3PL and they're newly acquired by
18 Cardinal and the drug was intrathecal
19 therapeutic medicine.
20 Q. What do you mean by 3PL?
21 A. A third-party logistics
22 provider, so that means they -- like they
23 pick, pack and ship on your behalf and they
24 keep the stuff in the warehouse for you so
25 you don't have to own your own warehouse.

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1 Q. Okay. Do you have any
2 understanding of opioid prescription rates in
3 the state of Tennessee?
4 A. No.
5 Q. Do you recall ever reviewing
6 any news articles about the opioid epidemic
7 in Tennessee?
8 A. No.
9 Q. Do you have an understanding
10 that the opioid epidemic is more acute in
11 some parts of the country than other parts of
12 the country?
13 A. Yes.
14 Q. What parts of the country is it
15 your understanding where the opioid epidemic
16 is particularly acute?
17 A. I have a limited understanding.
18 I hear a lot about West Virginia, and then in
19 general, maybe not a part of the country, but
20 the description of rural areas, it seems more
21 acute.
22 Q. When you reference West
23 Virginia, do you recall any references to the
24 opioid epidemic being particularly acute in
25 Appalachian areas?

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1 A. Yes.
2 Q. Are you aware that eastern
3 Tennessee is kind of the southern portion of
4 the Appalachia region?
5 A. Not really. I probably should
6 be.
7 Q. It's all right. If people ask
8 me about geography in Texas, I'd have to
9 plead ignorance too, so it's okay.
10 Have you ever reviewed any
11 materials published by the Tennessee
12 Department of Health?
13 A. Not that I can recall.
14 Q. In your time with Mallinckrodt,
15 did you ever have occasion to review
16 IMS Health data regarding opioid prescription
17 rates?
18 A. No. I can't recall ever
19 looking at any data, no.
20 Q. Do you recall during your time
21 with Mallinckrodt ever discussing any
22 specific pill mill operations in the state of
23 Tennessee?
24 A. No.
25 Q. You testified earlier today

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1 that you had heard of the term "Oxy Express."
2 Do you recall that?
3 A. I do.
4 Q. Do you know if that is a
5 reference to Interstate 75, which is an
6 interstate that runs through the state of
7 Florida up north?
8 A. That's my understanding, that
9 it's an interstate that runs from Florida to
10 kind of the northeast corridor. I'm not sure
11 if I would know the interstate number.
12 Q. Sure.
13 Do you have an understanding
14 that that interstate runs through eastern
15 Tennessee?
16 A. No, I don't know that.
17 Q. So I think, if I'm
18 understanding your testimony correctly, you
19 understand that the Oxy Express started in
20 Florida?
21 A. Yes.
22 Q. And it ran up a corridor along
23 an interstate through the northwest?
24 A. Through the northeast.
25 Q. Northeast.

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1 A. Yes.
2 Q. But you don't know the specific
3 states that it touched or the areas that it
4 went through?
5 A. No.
6 Q. In your role as director of
7 global customer service, did you interact
8 with law enforcement officials?
9 A. No.
10 Q. Do you ever recall talking to a
11 police officer from Morristown, Tennessee?
12 A. No, I don't.
13 Q. Do you ever recall any
14 discussions at Mallinckrodt regarding an
15 inquiry made from a police officer in
16 Morristown, Tennessee?
17 A. No, I don't.
18 (Discussion off the
19 stenographic record.)
20 (Mallinckrodt-Saffold
21 Exhibit 37 was marked for
22 identification.)
23 QUESTIONS BY MR. GASTEL:
24 Q. I'm going to hand you a
25 document that we'll mark as Exhibit 37.

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1 A. Thank you.
2 Q. Do you see that this is an
3 e-mail dated April 21st, 2011, from Mike
4 Santowski to you?
5 A. Yes.
6 Q. Do you recall receiving this
7 e-mail?
8 MR. MILLER: Is there a Bates
9 number on this document?
10 MR. GASTEL: Sure. It's
11 MNK-T1_0007114309.
12 QUESTIONS BY MR. GASTEL:
13 Q. And he's forwarding you an
14 e-mail that he had sent, Mr. Santowski had
15 sent, to Blanche Eder?
16 Do you see that?
17 A. Yes.
18 Q. Who is Blanche Eder?
19 A. I believe Blanche was an
20 administrative assistant, but I'm not sure to
21 whom.
22 Q. And it says: Blanche, for
23 Monday's EC meeting. I will have George make
24 copies for Monday.
25 Did I read that correctly?

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1 A. Yes.
2 Q. Is "EC meeting" a reference to
3 an executive committee meeting?
4 A. Yes.
5 Q. And who would typically attend
6 an executive committee meeting?
7 A. I don't know.
8 Q. Would you ever attend executive
9 committee meetings?
10 A. Only as an invited guest and
11 usually to maybe do a presentation and then
12 usually leave.
13 Q. Do you recall attending the one
14 that's referenced in this e-mail, April
15 of 2011? You can feel free to look through
16 the document.
17 (Document review by witness.)
18 A. No. I don't recall attending
19 this meeting.
20 QUESTIONS BY MR. GASTEL:
21 Q. Do you know why Mr. Santowski
22 might have asked you to make copies of this
23 or have you have Doris make copies of this
24 presentation?
25 A. I don't know for sure, but

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1 because I had an admin and I know there were
2 times where Michael didn't have an admin, so
3 he, you know, asked me to have my admin do
4 stuff because she -- you know, I reported to
5 him so he kind of shared her with me.
6 Q. And is Doris your admin?
7 A. She was, yes.
8 Q. She was at that time.
9 Let's flip to the PowerPoint
10 presentation that's attached to this e-mail.
11 A. Sure.
12 Q. Do you see how on the first
13 page, the cover page, it is entitled
14 Mallinckrodt Controlled Substance Suspicious
15 Order Monitoring Program?
16 A. I do.
17 Q. And it has a note here that
18 it's for the presentation for executive
19 committee of April 25th, 2011, right?
20 A. Yes.
21 Q. Would the executive committee
22 be the higher-up executives at Covidien
23 Mallinckrodt?
24 A. Yes.
25 Q. Would that be C-level --

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1 C suite level people?
2 A. I don't know the -- and I don't
3 recall the specific members of the executive
4 committee.
5 Q. But it would be people higher
6 than you in the organizational chart?
7 A. Yes.
8 Q. Would it be higher than
9 people -- than Mr. Santowski?
10 A. I really don't know if he was
11 executive committee or not.
12 Q. Sure.
13 Will you flip to page 4 of this
14 PowerPoint presentation?
15 A. Sure.
16 Q. And do you see that it's
17 entitled Florida Distribution of Oxycodone?
18 A. Yes.
19 Q. And it says: 98 of the top 100
20 doctors dispensing oxycodone nationally are
21 in Florida. By far, more oxycodone is
22 dispensed in the state of Florida than in the
23 remaining states combined.
24 Did I read that correctly?
25 A. Yes.

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1 Q. And, again, there's a reference
2 here that the data comes from the Florida
3 governor's press office of March 28, 2011.
4 Did I read that correctly?
5 A. Yes.
6 Q. And earlier today you went
7 through an e-mail with Ms. Keech showing that
8 Mallinckrodt eventually suspended orders to
9 five of its distributor customers.
10 Do you remember that e-mail?
11 A. Yes.
12 Q. And those five were KeySource,
13 Masters, Harvard, Cedardale and Sunrise,
14 right?
15 A. Yes.
16 Q. And that was related to
17 diversion activity going on in the state of
18 Florida, correct?
19 A. I don't know the --
20 MR. BERG: Object to form.
21 THE WITNESS: Sorry.
22 A. I don't know the specifics
23 around these accounts and why they're
24 suspended.
25 --oOo--

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1 QUESTIONS BY MR. GASTEL:
2 Q. But it sounded like you had
3 some role in implementing their -- the
4 suspension of sales of controlled substances
5 to those five organizations in 2011?
6 MR. BERG: Object to form.
7 A. I don't think I really had a
8 role in implementing the suspension of any
9 accounts.
10 QUESTIONS BY MR. GASTEL:
11 Q. Will you flip to page 6?
12 A. Yes.
13 Q. You see that this slide is
14 entitled DEA Distributor Initiative, 2008?
15 A. Yes.
16 Q. And it says: DEA suspends
17 licenses of distributors for not maintaining
18 effective controls against diversion of
19 controlled substances.
20 Did I read that correctly?
21 A. Yes.
22 Q. And there's a reference to an
23 AmerisourceBergen facility in Orlando,
24 Florida, correct?
25 A. Yes.

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1 Q. A reference to Cardinal paying
2 a \$34 million fine for actions -- in having
3 their license suspended at three distribution
4 centers?
5 Do you see that?
6 A. Yes.
7 Q. And there's also a reference to
8 McKesson paying more than \$13 million to
9 settle claims that it failed to report
10 suspicious sales of prescription medications.
11 Do you see that?
12 A. Yes.
13 Q. And those, I think you
14 referenced earlier today, are the Big Three?
15 A. Yes.
16 Q. And they remained the Big Three
17 from 2008 to the time that you left your role
18 at Mallinckrodt, right?
19 MR. BERG: Objection to form.
20 A. Yes.
21 QUESTIONS BY MR. GASTEL:
22 Q. In other words, they were the
23 three largest customers of Mallinckrodt for
24 controlled substances, right?
25 A. Yeah, they're the three largest

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1 customers of Mallinckrodt Pharmaceuticals.
2 Q. Will you flip to the next page?
3 There's a reference to Masters
4 Pharmaceutical.
5 Do you see that?
6 A. I do.
7 Q. And it says Masters is a
8 Mallinckrodt distributor customer?
9 A. Yes.
10 Q. And it says: Masters sold more
11 than 4 million doses of hydrocodone,
12 phentermine and alprazolam to internet
13 pharmacies between 2005 to 2008 without
14 reporting the sales to the DEA.
15 Did I read that correctly?
16 A. Yes.
17 Q. It says: Although Masters
18 reported suspicious orders during the
19 2005-2008 period in question, the DEA
20 believed that some orders placed by 10
21 pharmacies should have been reported as
22 suspicious.
23 Did I read that correctly?
24 A. Yes.
25 Q. It says they were fined

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1 \$500,000, right?

2 A. Yes.

3 Q. And this e-mail presentation

4 was apparently given to Mallinckrodt's

5 executive team just a few months before the

6 suspension went into effect for KeySource,

7 Masters, Harvard, Cedardale and Sunrise,

8 right?

9 MR. BERG: Object to form.

10 A. I'd have to kind of

11 cross-reference the dates. I don't really

12 recall -- I don't recall this presentation or

13 the circumstances around the suspension of

14 the five distributors you just named.

15 QUESTIONS BY MR. GASTEL:

16 Q. Sure. But the date on this

17 presentation is April of 2011, right?

18 A. Yes.

19 Q. And the date of the e-mail that

20 you were looking at with Ms. Keech earlier

21 was July of 2011, right?

22 A. Yes.

23 Q. So if the dates of these

24 documents are correct, then it appears that

25 this was given just a few months prior to

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1 Mallinckrodt suspending sales of controlled

2 substances to those five distributors, right?

3 A. Yes.

4 Q. So as early as 2011,

5 Mallinckrodt knew that its distributors were

6 getting in trouble with the DEA for their

7 failure to maintain effective controls

8 against diversion.

9 Would you agree with that

10 statement?

11 MR. BERG: Object to form.

12 A. As early as 2011, Mallinckrodt

13 knew that -- yes.

14 QUESTIONS BY MR. GASTEL:

15 Q. Do you know how many

16 Mallinckrodt orders to these distributors

17 were reported to the DEA during this time

18 period as suspicious?

19 A. No.

20 Q. Would you ask Karen Harper that

21 question if you needed to know the answer to

22 it?

23 A. If I had needed to know the

24 answer to that question, I would have asked

25 Karen Harper, yes.

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1 Q. Are you aware that Mallinckrodt

2 eventually entered into its own memorandum of

3 understanding with the DEA?

4 A. No.

5 Q. You weren't aware of

6 Mallinckrodt entering into such an agreement

7 with the DEA?

8 A. No, I'm not.

9 Q. Would it surprise you to learn

10 that that were true?

11 A. I mean, not, you know, I'm

12 going to be startled or alarmed, but yes.

13 Q. And I know you testified

14 earlier that you were on the Suspicious Order

15 Monitoring steering committee, right?

16 A. Yes.

17 Q. And you would occasionally

18 attend meetings, right?

19 A. Yes.

20 Q. I'm going to hand you a

21 document that we're going to mark as

22 Exhibit 38.

23 (Mallinckrodt-Saffold

24 Exhibit 38 was marked for

25 identification.)

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1 QUESTIONS BY MR. GASTEL:

2 Q. And this is an e-mail from

3 Jennifer Buist to John Gillies dated

4 December 12, 2012, 12/12/12. And attached to

5 it is some steering committee notes for that

6 date.

7 MR. MILLER: Is there a Bates

8 number on the document?

9 MR. GASTEL: Sure. It's

10 MNK-T1_0006967774.

11 QUESTIONS BY MR. GASTEL:

12 Q. Do you see that, sir?

13 A. Yes.

14 Q. Do you recall attending a

15 meeting of the steering committee on

16 December 12, 2012?

17 A. No, I don't.

18 Q. Do you ever recall the steering

19 committee -- if you flip to the last page of

20 this document, sir, there is a chart under

21 Jen Buist Statistics.

22 Do you see that?

23 A. Yes.

24 Q. And then there's a chart and it

25 says Order Lines Processed and Order Lines

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1 Failed.
2 Do you see that?
3 A. Yes.
4 Q. And then for a period from
5 March 2012 to November 2012, it adds up the
6 order lines processed and the order lines
7 failed.
8 Do you see that?
9 A. Yes.
10 Q. Your customer service
11 department was responsible for processing the
12 order lines, right?
13 A. No. I mean, if we entered a
14 manual order, yes, but there were a series of
15 edits and a lot of electronic orders that
16 then ran edits and -- that we didn't really
17 do or own.
18 Q. Sure. And we might be talking
19 past one another.
20 A. Okay.
21 Q. Happens all the time. I might
22 ask a bad question. I ask -- I do it all the
23 time. But what I mean is that when an order
24 line gets shipped, it's shipped by the
25 customer service department, right?

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1 A. No. An order is shipped -- I
2 mean, not to -- an order is shipped by our
3 shipping department, right, by our facility
4 in -- where the product is kept. Customer
5 service does not ship orders.
6 Q. Then who releases the order to
7 be shipped?
8 A. Well, if the order is
9 electronic, it flows through the system. If
10 an order is manual, customer service enters
11 the order and then if it passes the edits, it
12 will just flow through. And if an order has
13 field edits, typically it's customer service
14 that can release, like, something that was
15 held. But there may be others as well.
16 Q. Sure.
17 And what do you mean by passing
18 edits?
19 A. So there's all kinds of edits
20 that run over an order in the order
21 management system; unit of measure checks,
22 address matches, 222 number, you know,
23 restricted and unrestricted, a lot of edits
24 like that. So we kind of refer to those as
25 order integrity checks.

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1 Q. And then eventually, if those
2 orders pass all of that, that's when they're
3 released for shipment?
4 A. Yes. So after an order passes
5 all through those, then the order -- the
6 items on the order, then it looks at -- the
7 system will look at availability of the
8 product. And if the product is available in
9 the distribution center, then there's -- the
10 order activity rules govern this. So then
11 there's a -- a pick is generated. So then
12 the person in the distribution center goes
13 and picks the product and they -- there's a
14 process called pick confirm, and then they
15 put it in the packing area and there's a
16 practice called pack confirm. So it goes
17 through all these steps.
18 And then after it's
19 pack-confirmed, there's kind of a count to
20 make sure everything matched up, and then
21 following that, there's a ship confirm, which
22 basically means we put this on the truck.
23 And then that generates an invoice.
24 Q. And then once it's on the
25 truck, it's released?

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1 A. Well, I don't know -- I mean,
2 it's -- I don't know if there's like a
3 release -- I mean, once it's on the truck
4 it's already -- you know, it's gone through
5 those processes I named.
6 Q. Sure.
7 But once it's on the truck,
8 it's sort of out of Mallinckrodt's hands and
9 going to wherever it's supposed to go, right?
10 A. Sort of, but not really.
11 Because we also -- we also make sure that --
12 made sure that then it was delivered to the
13 right spot, including the signature of the
14 person and checking that up against a list of
15 who was authorized to receive that product
16 and ensured that happened.
17 And at that point I would say,
18 after we know they signed it, it was signed
19 for by the right person, it was delivered,
20 then I think it's fair to say, then it's
21 totally out of ours.
22 Q. But assuming that everything is
23 processed correctly, it's delivered
24 correctly, Mallinckrodt doesn't have the
25 hands on its product after it's on the truck?

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1 A. Yes, I think that's fair to
2 say.
3 Q. And then during that process
4 that you described, at some point it leaves
5 customer service's hands, right, and
6 essentially gets -- if I'm understanding your
7 testimony correctly -- placed in the hands of
8 the delivery production team, right?
9 A. Yes. Yeah.
10 Q. And then -- but if I'm
11 understanding your testimony correctly, all
12 of the lines that come in for an order go
13 through that customer service system, right?
14 A. No. I mean, so, you know,
15 customer service is only going to see orders
16 that we either enter or that have not passed
17 those edits and then are on an exception
18 report. You know, exception report for any
19 reason.
20 If an electronic order, which
21 is what probably 90% of what was ordered was,
22 if an electronic order went from EDI through
23 CSOS, everything was good, we had the
24 product, it went down to the DC, we would --
25 we wouldn't really see that order. It

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1 wouldn't be fair to say it was in customer
2 service.
3 Q. And then if it's not flagged by
4 the SOM algorithm, the electronic order --
5 A. Yes.
6 Q. -- it would go through the
7 process that you described of being packaged
8 and shipped and put on the truck, correct?
9 A. Yes.
10 Q. And I think that you testified
11 that the vast majority of the orders are
12 electronic, correct?
13 A. Yes.
14 Q. Was that true from the time
15 period of 2013 through present?
16 A. I certainly couldn't speak to
17 the present today.
18 Q. Sure.
19 A. But I can speak through my
20 tenure at Mallinckrodt. I don't know if --
21 the number of orders, but I could say the
22 quantity of product. Does that kind of --
23 because you're going to get -- onesie-twosies
24 are more likely to be manual, so you might
25 get a lot of onesie-twosie orders, but then

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1 if you get one electronic order it's going to
2 be a lot more product, typically.
3 Q. Sure.
4 So if I'm understanding your
5 testimony correctly, the majority of product
6 that gets shipped in the time period of 2012
7 to the time you left Mallinckrodt would have
8 been ordered electronically.
9 A. Yes.
10 Q. Do you have an understanding of
11 approximately how many order lines hit the
12 algorithm?
13 MR. BERG: Object to form.
14 A. No. Well, are you referring to
15 the Suspicious Order Monitoring algorithm?
16 QUESTIONS BY MR. GASTEL:
17 Q. Yes.
18 A. No. I don't really have a lot
19 of information about how that algorithm
20 functions.
21 Q. Sure.
22 (Mallinckrodt-Saffold
23 Exhibit 39 was marked for
24 identification.)
25 --oOo--

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1 QUESTIONS BY MR. GASTEL:
2 Q. I'm going to hand you a
3 document that has been marked as Exhibit 39.
4 And this is an e-mail from Matt Bell dated
5 October 8th, 2013, sent to a variety of
6 people. You're CC'd on it. You'll see that
7 you're the last name on the second-to-last --
8 third-to-last CC line.
9 Do you see that?
10 A. Yes.
11 MR. MILLER: Sorry. Is there a
12 Bates number on the document?
13 MR. GASTEL: MNK-T1_0004291190.
14 QUESTIONS BY MR. GASTEL:
15 Q. And the subject is Oxycodone
16 Orders.
17 Do you see that?
18 A. Yes.
19 Q. And it's a long e-mail chain,
20 but it starts, if you flip back to the
21 Bates-numbered page ending in 1193, it starts
22 with this e-mail from Jacob Longenecker on
23 October 3rd, 2013.
24 Do you see that?
25 A. Yes.

<p style="text-align: right;">Page 226</p> <p>1 Q. And it says: As we previously 2 discussed, we should see large oxy orders 3 today from McKesson and ABC. These orders 4 can be spaced out based on their historical 5 demand. 6 Did I read that correctly? 7 A. Yes. 8 Q. And then if you flip to the 9 next page after the chart, this is a 10 continuation of that same e-mail. 11 It says: Jennifer, these 12 orders will certainly set off a flag on your 13 end. Please allow the orders to process. 14 Did I read that correctly? 15 A. Yes. 16 Q. And if you go back to the 17 e-mail, the Jennifer referenced on the e-mail 18 is Jennifer Buist. 19 Do you see that? 20 A. Yes. 21 Q. So am I correctly interpreting 22 this document that when Jacob Longenecker 23 tells Jennifer that the orders are going to 24 set off a flag on your end, that he's 25 signaling that these orders would hit the</p>	<p style="text-align: right;">Page 228</p> <p>1 you know, some of this and instead you're 2 selling this and we want to know why, right? 3 Because your forecast doesn't match and our 4 production people are making the wrong stuff, 5 so why are we getting this order? 6 So I don't know -- because we 7 didn't want it to show on -- be backordered 8 if it's not really what we were intending to 9 sell. So -- and a lot of people on here 10 would have been, like, stakeholders in this 11 process. 12 Q. Sure. 13 And then going back to the 14 e-mail that you're covered on, it says: 15 Hello Jake and All. Updates below to the 16 shipping plan for the ABC and McKesson oxy 17 orders. 18 Do you see that? 19 A. Yes. 20 Q. And it says: After meeting 21 with the customer service management today, 22 it was decided the best way to approach the 23 suggested shipment weeks in my chart below is 24 to add lines to each of the purchase orders 25 we have received from ABC and McKesson. Then</p>
<p style="text-align: right;">Page 227</p> <p>1 algorithm? 2 MR. BERG: Object to form. 3 A. I'm not sure of that. You 4 know, sub- -- I just can't be sure, because 5 we did -- you know, we're pretty good at 6 forecast and supply stuff and, so, you know, 7 especially with some of the people on copy, 8 they're kind of planning kind of guys, and I 9 know that they ran stuff to say, like, your 10 forecast is bad or this is too much demand 11 and we shouldn't have to fill it, just 12 because of from like a fill rate and service 13 and production planning. 14 So I don't know if they're 15 really referring to the algorithm for 16 Suspicious Order Monitoring or not. 17 QUESTIONS BY MR. GASTEL: 18 Q. Do you know any other flag that 19 Jennifer Buist was responsible for other than 20 a Suspicious Order Monitoring flag? 21 A. Yeah, yeah. So they -- I can't 22 really recall like a name for it, but just of 23 what we would call excessive demand, not 24 Suspicious Order Monitoring but just, hey, 25 you know, you told me you were going to sell,</p>	<p style="text-align: right;">Page 229</p> <p>1 divide the items on the purchase order lines 2 by an equal amount for however many weeks I 3 suggested that we ship the total SKU demand. 4 Finally, enter appropriate case quantities 5 and request dates for each line corresponding 6 to the regular shipment date for ABC or 7 McKesson. 8 Did I read all that correctly? 9 A. Yes. 10 Q. Can you explain what any of 11 that means? 12 A. No. I don't really recall 13 this, and I'm not sure I understand what he's 14 doing here. 15 Q. And then -- but you don't -- 16 you see the reference to customer service 17 management? 18 A. Yes. 19 Q. Do you see any other customer 20 service folks on this e-mail other than you? 21 A. Yes. 22 Q. Who else is on there? Let me 23 strike that. Let me back up. 24 Do you see any other people 25 from customer service management on here</p>

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1 other than you?
2 A. I do.
3 Q. And who are those people?
4 A. Kris Quasebarth.
5 Q. I don't mean to be rude, sir,
6 but are you done?
7 A. Oh, yeah. I'm sorry.
8 Q. Okay. It's no problem. I just
9 didn't know if you were still looking for
10 names.
11 What was Kris Quasebarth's
12 role?
13 A. He was manager of dosage and
14 API customer service.
15 Q. Okay, I'm sorry. I thought
16 that only Mr. Rausch and Ms. Stewart were
17 managers of dosage.
18 A. So in 2013, neither Jim Rausch
19 nor Cathy Stewart reported to me anymore and
20 I don't think Jim was even part of the
21 company anymore. So Kris was the
22 replacement, and we consolidated API and
23 dosage kind of under one manager and that was
24 Kris.
25 Q. Got it. Was he still there

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1 when you left the company?
2 A. No.
3 Q. Who was in that role when you
4 left the company?
5 A. Amy Martinez.
6 Q. Are you aware that in or around
7 2007, McKesson had their license suspended by
8 the DEA in certain of its operations because
9 of McKesson's failure to maintain effective
10 controls against diversion?
11 A. No, I don't recall that. Also,
12 in 2007, I didn't really work with --
13 Q. Sorry. If I said 2007, I meant
14 2017.
15 A. Oh. Well, also in 2017, after
16 March of 2017, I didn't really do anything
17 with pharmaceuticals anymore. So, no, I was
18 not aware of that.
19 (Mallinckrodt-Saffold
20 Exhibit 40 was marked for
21 identification.)
22 QUESTIONS BY MR. GASTEL:
23 Q. I'll show you a document that's
24 been marked as Exhibit 40. And this is an
25 e-mail from Emily Breneman to you, Amy

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1 Martinez and Ashley Kitchen.
2 Do you see that?
3 A. Yes.
4 Q. It says McKesson Order
5 Restrictions is the subject line.
6 Do you see that?
7 A. Yes.
8 MS. WIDAS: Can you give the
9 Bates number of that, please.
10 MR. GASTEL: MNK-TNSTA --
11 sorry. MNK-TNSTA04824847.
12 QUESTIONS BY MR. GASTEL:
13 Q. Do you recall receiving this
14 e-mail, sir?
15 A. No.
16 Q. The e-mail starts with an
17 e-mail from Karen Harper on January 18th,
18 2017, to a variety of people. You're not on
19 that e-mail. But it's inviting folks to join
20 a conference meeting related to this attached
21 press release.
22 Do you see that?
23 A. Yes.
24 Q. And then the press release
25 apparently comes from the DEA Public Affairs

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1 Division.
2 Do you see that?
3 A. Yes.
4 Q. And it's titled McKesson agrees
5 to pay record \$150 million settlement for
6 failure to report suspicious orders of
7 pharmaceutical drugs.
8 Did I read that correctly?
9 A. Yes.
10 Q. And it's dated January 17th,
11 right?
12 A. Yes.
13 Q. Which would have been, I
14 believe, one day before the January 18th,
15 2017 e-mail that Karen starts this e-mail
16 chain with.
17 Do you see that?
18 A. Yes.
19 Q. And the press release states:
20 McKesson Corporation, one of the nation's
21 largest distributors of pharmaceutical drugs,
22 agreed to pay a record \$150 million civil
23 penalty for alleged violations of the
24 Controlled Substances Act, the U.S. Drug
25 Enforcement Administration announced today.

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1 Did I read that correctly?

2 A. Yes.

3 Q. "The nationwide settlement

4 requires McKesson to suspend sales of

5 controlled substances from its distribution

6 centers in Colorado, Ohio, Michigan and

7 Florida for multiple years. The staged

8 suspensions are among the most severe

9 sanctions ever agreed to by a DEA-registered

10 distributor. The settlement also imposes new

11 and enhanced compliance obligations on

12 McKesson's distribution system."

13 Did I read that correctly?

14 A. Yes.

15 Q. Does this refresh your

16 recollection at all about McKesson having

17 some of its controlled substances licenses

18 suspended by the DEA?

19 A. I really don't remember this.

20 Q. If you flip to the next page,

21 which I think is the last page, at the very

22 top it says: The government's

23 investigation -- I'm sorry.

24 A. Let me find it. Okay.

25 Q. Maybe it's not the last page.

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1 I'm sorry. Are you with me?

2 A. Yes.

3 Q. It says: The government's

4 investigation developed evidence that even

5 after designing a compliance program after

6 the 2008 settlement, McKesson did not fully

7 implement or adhere to its own program. In

8 Colorado, for example, McKesson processed

9 more than 1.6 million orders for controlled

10 substances from June 2008 through May 2013,

11 but reported just 16 orders as suspicious,

12 all connected to one instance related to a

13 recently terminated customer.

14 Did I read that correctly?

15 A. Yes.

16 Q. And that reference to the 2008

17 settlement, we saw in a previous PowerPoint,

18 Mallinckrodt was aware of based on that

19 executive committee presentation of April

20 2011.

21 Do you recall that?

22 A. Yes.

23 Q. And then here's another

24 instance of McKesson being -- having an

25 enforcement action undertaken by the DEA for

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1 its failure to comply with the Controlled

2 Substances Act, correct?

3 A. Yes.

4 Q. And then going back to the

5 e-mail that you're copied on, it says: Let

6 me know if you need any help from me with the

7 item restrictions for Lakeland. Thanks,

8 Emily.

9 Do you see that?

10 A. Yes.

11 Q. And then again, the e-mail

12 below that shows the Aurora, Colorado and

13 Livonia, Michigan accounts having their

14 schedule drugs removed today.

15 Do you see that?

16 A. Yes.

17 Q. And that would be January 20th,

18 2017, right?

19 A. Yes.

20 Q. And I assume that customer

21 service would have to get involved in this in

22 order to essentially flip off the switch to

23 allow orders of Mallinckrodt controlled

24 substances to go to these locations that

25 McKesson no longer had a DEA license for,

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1 right?

2 A. Well, you know, I'm not so

3 sure, to flip the switch. That's owned by

4 data integrity analysts and data integrity

5 department, so I think maybe even -- so I

6 don't think we would.

7 And then Emily reports --

8 reported to me in customer service, and I

9 think she's asking here, hey, do you need us

10 to, but I don't think we had to do much to

11 remove a schedule. I don't think we owned

12 that, that switch.

13 Q. And I'm sorry, in your opinion,

14 who owned that switch?

15 A. Data integrity.

16 Q. And who did they report to?

17 A. I don't know who data integrity

18 rolled up into. I think they were kind of

19 part of the finance org, but -- and I can't

20 recall the name of who kind of owned that

21 group.

22 Q. Do you know if any of

23 Mallinckrodt's shipments to these McKesson

24 facilities that had their license suspended

25 by the DEA were flagged by Mallinckrodt's

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1 algorithm as potentially -- or as peculiar
2 orders?
3 MR. BERG: Objection. Object
4 to form.
5 A. I don't know.
6 QUESTIONS BY MR. GASTEL:
7 Q. Do you know if Mallinckrodt
8 reported any of these -- any of its previous
9 orders to these McKesson distribution
10 facilities that had their licenses suspended
11 by the DEA, did Mallinckrodt report that --
12 any of those orders to the DEA as suspicious?
13 A. I don't know.
14 Q. And you would ask Karen Harper
15 those questions if you needed to know that?
16 A. Yes.
17 Q. Did it ever concern you that
18 Mallinckrodt's distribution customers were
19 getting into trouble with the DEA and --
20 well, strike that.
21 Did it ever concern you that
22 Mallinckrodt's distribution customers were
23 getting in trouble with the DEA?
24 MR. BERG: Object to form.
25 A. Yes.

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1 QUESTIONS BY MR. GASTEL:
2 Q. Did you ever bring that up in
3 any of the meetings that you had with the
4 Suspicious Order Monitoring steering
5 committee?
6 A. No.
7 Q. Do you ever recall it being
8 discussed?
9 MR. BERG: Object to form.
10 A. Yes. We're, at Mallinckrodt,
11 certainly our compliance team, they really
12 discussed, you know, hey, here's -- you know,
13 as you see in slides, I think it's evident,
14 the team likes to -- you know, chose to
15 discuss these actions because we want to make
16 people -- I think the intention was to raise
17 awareness of the importance of compliance.
18 QUESTIONS BY MR. GASTEL:
19 Q. Was there ever a discussion
20 retroactively to look back to see if the
21 algorithm was correctly flagging any of the
22 orders that the DEA was later penalizing
23 Mallinckrodt's distributors for?
24 MR. BERG: Object to form.
25 A. I don't recall any.

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1 QUESTIONS BY MR. GASTEL:
2 Q. Do you recall if there was ever
3 an attempt to make adjustments to the
4 algorithm to reflect that Mallinckrodt's
5 distribution customers were getting in
6 trouble with the DEA?
7 MR. BERG: Object to form.
8 A. I don't really recall any.
9 (Mallinckrodt-Saffold
10 Exhibit 41 was marked for
11 identification.)
12 QUESTIONS BY MR. GASTEL:
13 Q. I'm going to hand you a
14 document that we'll mark as Exhibit 41. And
15 this is an October 28, 2013 e-mail from Amy
16 Martinez to you titled Materials.
17 Do you see that?
18 A. Yes.
19 MR. GASTEL: And the Bates
20 number on it --
21 MR. MILLER: Bates number on
22 the document? Ah, thank you.
23 MR. GASTEL: -- is
24 MNK-T1_0007872732.
25 --oOo--

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1 QUESTIONS BY MR. GASTEL:
2 Q. And the body of the e-mail
3 says: Hi George. I meet -- and I think she
4 means met -- I met this morning with Ginger.
5 I will be scheduling some time to sit with
6 her to learn a little more about the generics
7 part of our business. Attached are some
8 resources that she shared. Amy.
9 Did I read that correctly?
10 A. Yes.
11 Q. Do you recall this e-mail?
12 A. No.
13 Q. Do you recall the Ginger that
14 she's referencing?
15 A. Yes.
16 Q. And do you know why Amy would
17 have been sending her training materials for
18 the generic part of the business?
19 A. Oh, no, I'm sorry. I think
20 Ginger sent Amy these materials.
21 Q. Got it. And then Amy was being
22 trained on the generic part of the business?
23 A. Yes.
24 Q. I'm sorry, I did flip those
25 around.

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1 And then Amy was forwarding
2 them on to you?
3 A. Yes.
4 Q. To make you aware that she had
5 been trained on these materials?
6 A. Yes.
7 Q. And then do you recall why you
8 asked her to be trained on these materials?
9 MR. BERG: Object to form.
10 A. So I didn't ask her to be
11 trained on these materials. I did ask her to
12 make sure she understood the generics
13 business. She was coming from the API
14 business and I wanted to make sure she had a
15 successful onboarding with responsibilities
16 for generics.
17 QUESTIONS BY MR. GASTEL:
18 Q. And why is that?
19 A. Because she was becoming the --
20 we're changing her role, so she was replacing
21 Kris as the manager of both generics and API.
22 Q. And do you see that the e-mail
23 attaches various PowerPoint presentations and
24 training materials?
25 A. Yes.

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1 Q. And the first PowerPoint
2 presentation is entitled Mallinckrodt
3 Pharmaceuticals Specialty Generics Overview,
4 10/13. I think it's the first page after the
5 e-mail.
6 A. Yes.
7 Q. Do you see that?
8 A. I do.
9 Q. Will you flip to --
10 unfortunately, the pages aren't marked, but
11 will you flip to the graph that has Proposed
12 Generic Total Market Sales?
13 A. Yes. I think I'm there. Okay,
14 I'm there.
15 Q. It says Projected Generic Total
16 Market Sales in billions of dollars.
17 Do you see that?
18 A. Yes.
19 Q. And then there's a chart here
20 that shows that in 2008, the generic market
21 was approximately \$60 billion?
22 Do you see that?
23 A. In 2008, yes.
24 Q. And then in 2016, it was
25 projected to grow to \$100 billion.

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1 Do you see that?
2 A. Yes.
3 Q. And the source of this material
4 was apparently IMS Health pharmaceutical
5 data.
6 Do you see that?
7 A. Well, it looks like there are
8 several sources.
9 Q. Sure.
10 A. IMS Health, PhRMA, AC Nielsen,
11 the FDA and then a few others as well.
12 Q. Sure.
13 And then on the next page,
14 there's a chart?
15 A. Yes.
16 Q. And it says Key Competitors for
17 Mallinckrodt Products.
18 Do you see that?
19 A. Yes.
20 Q. And Actavis is listed having
21 apparently \$2.3 billion in sales.
22 Do you see that?
23 A. Yes.
24 Q. And then Mallinckrodt is next
25 with \$770 million in sales.

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1 Do you see that?
2 A. Yes.
3 Q. And the source of this material
4 was IMS?
5 MR. BERG: Object to form.
6 QUESTIONS BY MR. GASTEL:
7 Q. Do you see that?
8 A. Yes.
9 Q. And then if you will flip to --
10 maybe there are page numbers. Page 11?
11 A. Oh, got it.
12 Q. And it says Products Driving
13 Net Sales.
14 Do you see that?
15 A. Yes.
16 Q. And it says in millions.
17 Do you see that?
18 A. Yes.
19 Q. And it's a pie graph.
20 Do you see the pie graph?
21 A. Yes.
22 Q. And in the upper right-hand
23 corner, there is a section of the pie that
24 says Methylphenidate.
25 Do you see that?

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1 A. Yes.
2 Q. And that is apparently the
3 largest net sale here, correct?
4 A. Yes.
5 Q. And are these Mallinckrodt
6 generic products?
7 MR. BERG: Object to form.
8 A. Yes. Well, I don't know.
9 These are all products Mallinckrodt sold,
10 yes.
11 QUESTIONS BY MR. GASTEL:
12 Q. That's what I mean.
13 A. But I don't know if this is
14 exclusive to Mallinckrodt, no.
15 Q. Sure.
16 And then hydrocodone at
17 120 million is the next largest chunk of the
18 pie?
19 A. Yes.
20 Q. And oxycodone/oxycodone APAP is
21 the next largest chunk?
22 A. Yes.
23 Q. Right? And the fentanyl patch
24 is the next largest chunk?
25 A. Yes.

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1 Q. And then the morphine ER is the
2 next largest chunk.
3 Do you see that?
4 A. Yes.
5 Q. And those last four, those are
6 all opioids, right?
7 A. Yes.
8 Q. Was it your understanding in
9 your time at Mallinckrodt that Mallinckrodt
10 generic opioids were approximately half or
11 more than half of the net sales for generic
12 products at Mallinckrodt?
13 A. Yes.
14 MR. GASTEL: Mr. Saffold, I'm
15 sure this will be music to your ears,
16 but that's all the questions I have
17 for you, subject to my earlier
18 objection. We'll reserve the right,
19 but that's all I have for you today.
20 THE WITNESS: Okay. Thank you.
21 THE REPORTER: Anything
22 further?
23 MR. BERG: No questions.
24 THE VIDEOGRAPHER: Off the
25 record at 3:50.

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1 (Deposition recessed at
2 3:50 p.m.)
3 --oOo--
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1 CERTIFICATE
2
3 I, SUSAN PERRY MILLER, Registered
4 Diplomat Reporter, Certified Realtime
5 Reporter, Certified Court Reporter and Notary
6 Public, do hereby certify that prior to the
7 commencement of the examination, GEORGE
8 SAFFOLD was duly sworn by me to testify to
9 the truth, the whole truth and nothing but
10 the truth;
11 That pursuant to Rule 30 of the
12 Federal Rules of Civil Procedure, signature
13 of the witness was not reserved by the
14 witness or other party before the conclusion
15 of the deposition;
16 That the foregoing is a verbatim
17 transcript of the testimony as taken
18 stenographically by and before me at the
19 time, place and on the date hereinbefore set
20 forth, to the best of my ability.
21 I DO FURTHER CERTIFY that I am
22 neither a relative nor employee nor attorney
23 nor counsel of any of the parties to this
24 action, and that I am neither a relative nor
25 employee of such attorney or counsel, and
that I am not financially interested in the
action.

Susan Perry Miller
CSR-TX, CCR-LA, CSR-CA-13648
Registered Diplomat Reporter
Certified Realtime Reporter
Certified Realtime Captioner
NCRA Realtime Systems Administrator
Notary Public, State of Texas
My Commission Expires 03/30/2020
Dated: 12th of February, 2019

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